

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY

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6 : DEPOSITION DESIGNATION
7 : HEARING VIA TEAMS
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IN RE: VALSARTAN PRODUCTS
LIABILITY LITIGATION

Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, New Jersey 08101
October 3, 2024
Commencing at 10:31 a.m.

B E F O R E: THOMAS I. VANASKIE (RET.)
SPECIAL MASTER

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1 (PROCEEDINGS held in open court before SPECIAL
2 MASTER THOMAS I. VANASKIE at 10:31 a.m.)

3 SPECIAL MASTER VANASKIE: Where did you want to
4 start? Because maybe we're not on the same page there. I see
5 I've got Jacob and Daniel.

6 And where did you want to start?

7 MR. NIGH: Your Honor, we can leave it up to you, but
8 we've got Jaiswal and we've got the four witnesses. So we've
9 got about 60 pages of Jaiswal.

10 I did want to say to Your Honor that I also have a
11 medical appointment that I have to leave for at 12:20 Eastern.

12 SPECIAL MASTER VANASKIE: Okay.

13 MR. NIGH: It's not -- it's something that I just
14 kind of got last -- you know, short notice.

15 SPECIAL MASTER VANASKIE: Well, we want to have that
16 taken care of.

17 But who are the four witnesses?

18 Is Jaiswal the 40-page excerpt?

19 MR. NIGH: Yes.

20 MR. RAE: Yes.

21 MR. NIGH: 46 pages.

22 MR. RAE: And just, you know, a few scattered
23 segments of those 40 pages, so...

24 THE COURT: I think that's what we'll need to focus
25 on.

1 We can do Jaiswal first and then move to some of the
2 others.

3 But let me pull up his transcript. And that's from
4 June 25th. Right?

5 MR. NIGH: Yes.

6 SPECIAL MASTER VANASKIE: It's just loading now.

7 So I'm at page 831 of that transcript over here.

8 I really didn't have -- maybe I have it and I just
9 didn't see it -- pages from his -- specific pages. I just
10 knew it was that page range.

11 MR. NIGH: Your Honor, these were supplied in the
12 original that we had sent back on --

13 SPECIAL MASTER VANASKIE: Let me pull that up then.
14 That'll be helpful.

15 MR. NIGH: I will forward it again to Your Honor as
16 well so you have it top of inbox.

17 SPECIAL MASTER VANASKIE: Yeah, if you could forward
18 that to me again, Daniel.

19 MR. NIGH: Okay. I just sent it.

20 SPECIAL MASTER VANASKIE: Just waiting for it to come
21 through.

22 MR. NIGH: No problem.

23 SPECIAL MASTER VANASKIE: All right. I have it now.

24 MR. RAE: Okay. And, Your Honor, this is --

25 SPECIAL MASTER VANASKIE: I'll make sure I'm on the

1 right page.

2 We should be at page 831 of his transcript.

3 MR. NIGH: Yes, Your Honor.

4 SPECIAL MASTER VANASKIE: Lines 14 to page 832,
5 line 8.

6 MR. RAE: Yes, Your Honor.

7 Our first objection had been at 832, lines 6 to 12.

8 But to help speed things along here, I think we're
9 willing to withdraw our objections on -- starting on 832,
10 lines 6 through 833, line 7.

11 And so the first objection that I think it makes
12 sense for us to address is our objection to the question and
13 answer at 813, line 14 to 18.

14 SPECIAL MASTER VANASKIE: So we're on to page 833,
15 line 14.

16 Question: So in May of 2017, this is about a year
17 before Torrent learned its valsartan API was contaminated with
18 NDMA. Right?

19 That question and answer?

20 MR. RAE: Yes, Your Honor.

21 SPECIAL MASTER VANASKIE: And what's the basis for
22 the objection?

23 MR. RAE: This question misstates the record in a
24 prejudicial way. The "about a year" is not factually
25 accurate. Torrent didn't learn that its API was

1 contaminated -- like -- or that its API contained an NDMA
2 impurity until August of 2017, which is a meaningful amount
3 longer than a year after May of 2017. And so this question
4 kind of improperly implies that Torrent learned of the NDMA
5 impurity in the valsartan API that Torrent was purchasing
6 earlier than it actually did.

7 SPECIAL MASTER VANASKIE: You're saying they learned
8 in August of 2018, and that's --

9 MR. RAE: Right. This is a critical issue in the
10 case. This distinction between what was learned in June of
11 2018 about new process API and what was learned in August of
12 2018 about old process API.

13 SPECIAL MASTER VANASKIE: All right. Daniel?

14 MR. NIGH: Your Honor, this is, again, it's about a
15 year. I think they're drawing too much of a distinction here.
16 Any kind of confusion that this might mislead. Remember we
17 had a timeline that we're submitting? So they can all see the
18 timeline. I think that would have made it even clearer,
19 especially once we cleaned up that one misstatement. But on
20 top of that, there's been many questions and answers on the
21 time frame here, so I don't think that "about a year" misleads
22 anybody.

23 SPECIAL MASTER VANASKIE: Yeah. I don't really find
24 that misleading, so I'll overrule the objection.

25 What is next?

1 MR. RAE: It's the question that begins at the bottom
2 of this page on 833, line 23 and then runs through 834,
3 line 5.

4 SPECIAL MASTER VANASKIE: All right. So the question
5 is: And also that -- in May of 2017 that Torrent's valsartan
6 is contaminated with NDMA?

7 And the answer is: Yeah. They notified us regarding
8 this.

9 What's the basis for the objection?

10 MR. RAE: The objection here is largely the fact that
11 this, again, is confusing timelines by asking -- the way that
12 the question is phrased, it could imply that Torrent knew that
13 there was NDMA in its valsartan in May of 2017, which is not
14 the case. And so we think there's a significant risk of juror
15 confusion in the way this question is phrased.

16 SPECIAL MASTER VANASKIE: All right. Daniel?

17 MR. NIGH: The question actually doesn't speak to
18 knowledge in May of 2017. It's actually just, again, this is
19 sort of that understanding that the product that has been made
20 in 2017 is actually contaminated with NDMA, which is true.
21 There's nothing in the question that says that they knew about
22 it in 2017. It's talking about the product made in 2017 was
23 contaminated with NDMA.

24 MR. RAE: Your Honor --

25 SPECIAL MASTER VANASKIE: -- the answer, that

1 confuses the issue, because the witness answers: Yeah. They
2 notified us regarding this.

3 Go ahead, Jacob.

4 MR. RAE: I was going to agree that there's nothing
5 in this question that makes it clear that this is about --
6 that makes it clear what time frame or whether or not this is
7 about knowledge. And that's why there was a form objection
8 made to the question at the time and why there's a problem
9 with this question.

10 If the question was clearly oriented in one direction
11 or the other, it would be a perfectly fine question. The
12 problem is that the question is unclear. The witness's answer
13 doesn't provide clarity as to exactly what is being spoken
14 about and that creates the risk of confusion is the basis of
15 our objection.

16 SPECIAL MASTER VANASKIE: I agree. I'll sustain the
17 objection.

18 MR. NIGH: Your Honor, just to make it clear, the
19 question above I think is already switched from knowledge. We
20 know -- and that's why the next question makes sense, because
21 the question above says: And in May of 2017, we know that
22 Torrent is manufacturing valsartan with ZHP API. Right?

23 And then the next question is: And now -- and that
24 in May of 2017 that Torrent's valsartan is contaminated with
25 NDMA.

1 So that's what makes it clear. The question above
2 makes it clear that we're not switching gears here
3 immediately.

4 SPECIAL MASTER VANASKIE: I know. It is a little bit
5 confusing. I'll sustain the objection.

6 Are we proceeding to page 843 now?

7 MR. NIGH: Yes.

8 MR. RAE: Yes, Your Honor.

9 SPECIAL MASTER VANASKIE: And this is starting at
10 line 21.

11 MR. RAE: Yes, Your Honor. Our primary objection
12 here is a 602 objection to foundation.

13 The issue here is this is -- as Your Honor will
14 recall, this deposition was of Dr. Jaiswal in his personal
15 capacity and is following on the heels of a deposition of him
16 in his 30(b)(6) capacity, where he was shown certain documents
17 related to these inspection -- these EIRs that were conducted
18 of ZHP that at -- during his 30(b)(6) deposition he testified
19 he had never seen before.

20 And he's now being asked personal knowledge questions
21 about comparing these documents that his basis for knowing the
22 answers to these questions is because plaintiffs' counsel
23 showed them to him during his 30(b)(6) deposition.

24 SPECIAL MASTER VANASKIE: All right. Daniel --

25 MR. RAE: And so --

1 SPECIAL MASTER VANASKIE: Go ahead. Continue, Jacob.

2 MR. RAE: No. I can wrap up there, Your Honor.

3 Thank you.

4 MR. NIGH: Your Honor, I don't agree with how that's
5 positioned in terms of he doesn't have any knowledge of these
6 issues.

7 But, nonetheless, even if that were true, this
8 deposition takes place 20 days later. And even if he were
9 shown documents, he could still compare the information and
10 then in the citations and then between 2017 and 2018 and see
11 that there are similar citations between them.

12 So whether or not he had seen those two documents or
13 not would be irrelevant. But, nonetheless, he had seen them
14 20 days prior at least. And the question is: Did you know
15 that?

16 And he says: I'm aware of that. That's --

17 SPECIAL MASTER VANASKIE: I think it's proper. This
18 objection I will overrule.

19 What's the next one, Jacob?

20 MR. RAE: It is page 848 -- or, actually, the next is
21 we have a counter at page 846, line 10 through the 847,
22 line 24.

23 MR. NIGH: Your Honor, we don't have -- we're
24 withdrawing our objection to that counter.

25 SPECIAL MASTER VANASKIE: All right. Then what's

1 next?

2 MR. RAE: We have an objection at 848, line 2 to
3 line 10.

4 SPECIAL MASTER VANASKIE: So the question at 848,
5 line 2 is: So as head of quality of Torrent, after seeing
6 this report or learning these citations, Torrent never
7 followed up with ZHP to conclude whether or not this was
8 accurate. It continued to manufacture API from ZHP.

9 MR. RAE: Yes, Your Honor. And in light of
10 plaintiffs' counsel withdrawing their objection to our
11 counter, which we think provides the context to avoid
12 confusion in this designation, we'll withdraw our objection
13 here.

14 SPECIAL MASTER VANASKIE: Very well. Good.
15 Are we now up to page 853?

16 MR. NIGH: We are withdrawing our objections to each
17 of the counters -- the three counters made at page 846,
18 line 10 to 846, line 22; 846, line 23 to 847, line 4; and 847,
19 line 7 to page 848, line 1.

20 SPECIAL MASTER VANASKIE: All right.

21 MR. NIGH: The three counters there, we're
22 withdrawing all objections to those.

23 MR. RAE: Yes, Your Honor. There's an objection on
24 page 851, lines 16 to 17, which I think is similar to some of
25 the other objections we've talked about before, where

1 plaintiffs are designating attorney commentary that doesn't
2 follow up into the form of a question or designate an answer
3 to it.

4 MR. NIGH: This is just directing to where on the
5 page the witness --

6 SPECIAL MASTER VANASKIE: Yeah. I'll overrule the
7 objection. That introductory language is all right.

8 MR. RAE: Just for clarity, is -- the only scope of
9 the designation here, does it stop at page 14 and not include
10 the "okay, we're just going to highlight" portion of that
11 line?

12 MR. NIGH: Page 9, no. We're looking at page 14. I
13 think that that's fair, we'd stop there.

14 MR. RAE: Okay. Understood then.

15 I think we would not have objected to that without
16 the rest of the line.

17 MR. NIGH: Okay.

18 SPECIAL MASTER VANASKIE: So you're stopping at --
19 we're looking at page 14?

20 MR. NIGH: Yes.

21 SPECIAL MASTER VANASKIE: Okay.

22 MR. RAE: Our next objection is page 854, line 12
23 to -- and then it runs through 855, line 1.

24 And we have a couple of objections here. The first
25 is a form objection that we made at the time. This is a

1 compound question. There's two different questions being
2 asked here, and it's unclear which one the witness is
3 answering. There's kind of a preamble of: Now I understand.
4 You said this is meant to be corrected after an inspection,
5 but do you also understand that ZHP was further inspected by
6 the FDA again in 2018 and the same conclusions were found
7 about your API manufacturer?

8 There's then a form and foundation objection made. A
9 subsequent question is asked, which is just: You're aware of
10 that? Which does nothing to clarify and maybe introduces
11 further confusion to the prior questions.

12 The same objections are made, and the witness simply
13 answers: You're correct.

14 And I think it's unclear what the witness is
15 answering "you're correct" to, whether or not it's the
16 prefatory material that counsel provided to the question or
17 the question about understanding the similarities that -- like
18 there was a similar inspection.

19 SPECIAL MASTER VANASKIE: Daniel?

20 MR. NIGH: I think, you know, if there are a number
21 of things on a question when you say, and then you're aware of
22 that, and the witness says, yes, I am, that implies he's aware
23 of each of the things that's in the question.

24 So that's not a -- that ends up not being a compound
25 question or misleading as soon as he responds that, yes, I'm

1 aware of that.

2 SPECIAL MASTER VANASKIE: I think it is confusing and
3 misleading. I think it is definitely compound.

4 I'll sustain the objection.

5 MR. NIGH: What specifically is sustained? Is it
6 just 854:12 to 17?

7 SPECIAL MASTER VANASKIE: 854:12 to 17 and then the
8 answer that starts at the bottom of page 854, line 24 going
9 over to 855, line 1. All right?

10 I think we go to page 860, line 19 now.

11 MR. RAE: And, Your Honor, we have -- our objection
12 here is a mix of compound question issue or, you know, an
13 issue with the argumentative form of the question, attorney
14 narrative as well as a 403 objection. So there's a couple of
15 different issues that I want to unpack here.

16 The first is this question begins with counsel
17 reading a long paragraph from this EIR report that was issued
18 by the FDA to ZHP and then proceeds to ask a question that's
19 somewhat disconnected from the material that was just read
20 that is: Now, let me ask you, are you aware that ZHP
21 referenced these just as ghost peaks and ignored them?

22 There's a couple of issues with that. Like, one is
23 the layering in of -- I think the passage that's read to the
24 witness includes the FDA describing how an employee at ZHP
25 referred to certain test results as ghost peaks, but it does

1 not establish any information about them being ignored. So
2 there's a huge prejudice problem with this question, that it
3 layers in an assumption in the question that doesn't have a
4 foundation in the document, that there's no reason why this
5 witness would have any knowledge of whether or not ZHP did or
6 did not ignore ghost peaks and asks a Torrent witness to
7 confirm conduct by ZHP that he has no personal knowledge of,
8 he doesn't have awareness of.

9 And his answer of, no, I'm not aware, carries an
10 extreme risk of prejudice, frankly, to ZHP in this case due to
11 the fact that plaintiffs are asking him a question about what
12 ZHP ignored that he doesn't have any personal knowledge of and
13 he's simply answering that he doesn't have personal knowledge
14 of that.

15 SPECIAL MASTER VANASKIE: Daniel?

16 MR. NIGH: Your Honor, we specifically point to the
17 issue that's being raised in the question, those specific
18 paragraphs, and then ask him if he's aware of these issues.
19 So at this point, you know, he says he's not aware. I mean,
20 he could have clarified the question in any way he would --
21 the answer in any way he wanted to.

22 SPECIAL MASTER VANASKIE: I know it gets a little
23 confusing, especially when you read parts of a report and then
24 follow up with a question, but I think -- I certainly
25 understood it at the time, and I have to confess that I

1 understood his answer as saying he's not aware that ZHP
2 referenced these peaks as ghost peaks, not that they ignored
3 them.

4 That, to me, is more the problem, because the answer
5 could be interpreted as he was not aware that they ignored the
6 peaks or that they referred to it as ghost peaks.

7 So I've talked myself into sustaining this objection.

8 MR. NIGH: Okay.

9 SPECIAL MASTER VANASKIE: All right. What's next,
10 Jacob?

11 MR. RAE: We are now at 876, line 18 through 877,
12 line 6.

13 And this is the last one for Dr. Jaiswal as well.

14 And I think the issue here is the way in which this
15 question is phrased, it really mischaracterizes the nature of
16 these observations that the FDA makes in EIRs and 483 warning
17 letters.

18 The way in which these work is there's a high level
19 categorization of the observation that kind of fits CGMP
20 categories in a general way, and then the FDA elaborates in
21 detail on what specifically was the problem.

22 And the issue here -- and it kind of is also an issue
23 in earlier lines of questioning, but it's highlighted, like,
24 here, is plaintiffs are asking questions just about those high
25 level categorizations and the fact that those remain similar

1 across different documents and across different inspections,
2 which, of course, they do because they're the high level
3 categorizations that observations are always framed under.
4 They're not asking whether or not the actual observations that
5 are being made in these different EIRs or 483 warning letters
6 are actually the same, whether or not the actual issues that
7 the FDA is observing remain the same over time, only whether
8 or not the broad group that they're being categorized under is
9 remaining the same.

10 And it's similar to --

11 SPECIAL MASTER VANASKIE: You lost me on this one,
12 Jacob.

13 MR. RAE: So, Your Honor, the issue is, this is
14 asking for a comparison of observations that are being made
15 about ZHP's manufacturing facilities for valsartan API and
16 comparing those to Torrent's manufacturing facilities for
17 finished dose valsartan.

18 The problem is, it's implying that similar
19 observations were being made across those two facilities.
20 That's only true at an extremely high level of comparing the
21 kind of categorization that the FDA is using to describe these
22 reports. The actual content of the observations are about
23 completely different things.

24 MR. NIGH: Your Honor, I would just say that this is
25 highly probative at the outset of this. 483 obviously takes

1 into account the probative value. And whatever the -- you
2 know, the misunderstanding -- in fact, it's not even what it's
3 saying. It says: For failing to use scientific justification
4 to invalidate its lab specification reports.

5 It goes specifically to what the issue was. And then
6 it says: For Torrent, failing to establish scientifically
7 sound and appropriate test measures.

8 So those are the specific findings in each of those,
9 and it shows the timing is happening at the same time. It's
10 highly probative.

11 SPECIAL MASTER VANASKIE: Jacob, what specifically
12 are you objecting to? Give me the page and line numbers.

13 MR. RAE: The question at 876, line 18 to -- that
14 runs through the answer on 877, line 6.

15 And, Your Honor, another issue that kind of exists in
16 this designation ties back to joint defense motion in
17 limine 2, which is the citation of Torrent for failing to
18 establish scientifically sound and appropriate test measures.

19 Mr. Nigh can correct me if I'm misspeaking on this,
20 but I do not believe that that is related to Torrent's
21 manufacturing of valsartan.

22 And so this question runs afoul of that motion in
23 limine ruling, because this is not actually tied to
24 observations being made about Torrent's manufacturing of
25 finished dose valsartan. It's observations that relate

1 generally to Torrent's manufacturing at the Indrad facility,
2 which manufactures dozens, probably hundreds of different
3 products. I'm, frankly, not sure of the exact number of
4 products that are manufactured there.

5 MR. NIGH: Your Honor, it's 2017. It's the Indrad
6 facility that's manufacturing valsartan. There's a reason we
7 haven't withdrawn our objections related to the 2017 Torrent
8 inspection report, because some of those findings are
9 specifically related to even the valsartan. They cite
10 valsartan out-of-spec testing.

11 So, no, I think that it's -- I think it's highly
12 probative. I believe that -- and on top of that, keep in mind
13 this is the head person on quality at the company who is
14 responding to this. And he says: I understand that.

15 SPECIAL MASTER VANASKIE: This is -- go ahead, Jacob.
16 This is a 403 objection, though. Right?

17 MR. RAE: Yes, Your Honor. I just want to correct
18 the record on one thing. The 2017 EIR mentions valsartan in
19 exactly two places. It mentions that the 2016 FDA EIR that
20 had been conducted had specifically looked into valsartan. So
21 it mentioned it retrospectively in describing the last
22 inspection that the FDA had done of the Indrad facility.

23 And it mentions it with respect to one set of test
24 results that the FDA was looking at where it looked at test
25 results that related to several products, including valsartan,

1 and finds that there are no discrepancies with those test
2 results.

3 So the only specific reference to valsartan in the
4 2017 EIR, other than kind of retrospective discussion of the
5 correction of observations that had been made in 2016, is to
6 note that there was no issue with the one instance in which
7 the FDA looked into something that's specifically related to
8 valsartan.

9 SPECIAL MASTER VANASKIE: Well, the question before
10 me, as I understand it, is whether this question and the
11 answer that follows, the prejudice from it substantially
12 outweighs its probative value.

13 And I don't see it. So I'll overrule the objection.
14 All right?

15 Is that it for this witness, for Mr. Jaiswal?

16 MR. RAE: Yes, Your Honor. That's it for
17 Dr. Jaiswal.

18 SPECIAL MASTER VANASKIE: Okay. What other Torrent
19 witnesses do we have?

20 MR. RAE: We have four more Torrent witnesses.
21 They're all relatively small witnesses in terms of the -- both
22 volume of designations and objections. They're Reddy
23 Neravetla, Kalpesh Patel, Susan Perry and Paras Sheth.

24 SPECIAL MASTER VANASKIE: All right. I am ready for
25 them. That's what I want to make sure.

1 Let's go to Reddy.

2 MR. RAE: Your Honor, our first objection is at
3 page 100, line 2 to 13.

4 SPECIAL MASTER VANASKIE: Give me a second to get
5 everything up in front of me again.

6 What page is that, Jacob?

7 MR. RAE: Page 100, lines 2 to 13.

8 SPECIAL MASTER VANASKIE: All right. I'm with you.
9 What's the basis for the objection?

10 MR. RAE: So Mr. Neravetla is testifying as a
11 30(b)(6) witness on a single topic, which was tracing of
12 batches and lots of Torrent's valsartan finished dose sold
13 downstream and ultimately intended for use by consumers in the
14 United States.

15 And this is well outside the scope of that topic.

16 It's also testimony that is cumulative and
17 unnecessary at this point. Your Honor has already seen
18 designations from I believe every other Torrent witness that
19 we've looked at with Your Honor where plaintiffs are
20 designating questioning of witnesses about whether or not NDMA
21 is carcinogenic, whether or not it's genotoxic, the same line
22 of questioning. There's no need for that line of questioning
23 to be presented to every witness, particularly a witness like
24 Mr. Neravetla whose role at Torrent, as it was relevant here,
25 related to overseeing administrative aspects of the recall of

1 these products rather than kind of quality issues.

2 SPECIAL MASTER VANASKIE: Daniel?

3 MR. NIGH: Your Honor, Reddy Neravetla is the quality
4 assurance complaint investigator. The 30(b)(6) topic is
5 specifically -- and I'll read it in full.

6 Torrent's product recall for valsartan finished dose,
7 including who Torrent communicated with, how, about what, and
8 the retention of the sequestered valsartan finished dose.

9 So that second part in the retention of recalled or
10 sequestered valsartan finished dose, I don't know that we've
11 even designated anything for that.

12 But who Torrent communicated with, how, about what,
13 all that goes into -- you know, this would be highly relevant
14 in terms of those communications, what he knows.

15 MR. RAE: Your Honor, this is not about who Torrent
16 communicated with, how or about what. This is about the
17 witness's personal knowledge of information that's being --
18 that's already kind of being asked about through other
19 witnesses. That's really something that's an appropriate
20 topic for expert testimony, not for fact witness testimony,
21 and certainly not for fact witness testimony by someone who
22 doesn't have kind of specific personal knowledge related to
23 toxicology or chemistry or the other issues that would impact
24 kind of understanding of whether or not a given substance is
25 carcinogenic or capable of causing cancer.

1 MR. NIGH: And just to be clear, there is also a 403,
2 and I just want to make this clear so that it's understood,
3 because I saw some submissions.

4 We have held aside the objections related to how much
5 we're going to speak about on carcinogen and does it cause
6 cancer in humans.

7 We understand that the Court needs to rule on those
8 issues.

9 On the plaintiffs' side, we actually believe it
10 should be more limited in what comes in, and so that's been
11 understood. But we have to see where the judge makes a
12 ruling, and then we would de-designate all these issues based
13 on that ruling, so where the line is drawn.

14 So I just want to make that very clear. That doesn't
15 mean that we're a proponent of making the line wider in scope
16 in terms of what comes in on cancer and causation. But until
17 we know the line, we have had these designated, getting
18 rulings from Your Honor, then we would see where the judge
19 draws the line.

20 SPECIAL MASTER VANASKIE: Why do you need to ask this
21 witness the question -- those questions?

22 MR. NIGH: It's foundational to -- you know, the
23 question is -- again, the 30(b)(6) topic is Torrent's product
24 recall for valsartan finished dose, including who Torrent
25 communicated with, how, and about what. And I underline how

1 and about what. It's foundational on those issues.

2 SPECIAL MASTER VANASKIE: Well, it seems to me that
3 this is not going to be a controversial matter overall, that
4 is, that NDMA is a carcinogen. Maybe I'm wrong on that. But
5 my inclination is to allow it, just because it's going to be
6 in anyway. And whether -- is it Dr. Neravetla? I'll give up
7 trying to pronounce it. Dr. Reddy?

8 MR. RAE: I do not know off the top of my head
9 Mr. Neravetla's educational background. I do know that his
10 role at Torrent is not one of being a scientist, that he has
11 two roles at Torrent: That he oversees contract
12 manufacturers, which Your Honor will recall are the people --
13 like, where Torrent contracts out the creation of its finished
14 doses product. He oversees that department at Torrent. And
15 then he oversees recall-related issues in a role of kind of
16 administering the recall process and handling the
17 communications with retailers and other people when notices
18 have to get sent out and the logistics of managing kind of --
19 as you know, like a recall involves a lot of logistical
20 issues. His role is to oversee the department that handles
21 that sort of thing.

22 MR. NIGH: Yeah. And I would just come back to, Your
23 Honor, on our side, we have -- we take on connecting it up
24 from the information that's known -- because that's the way in
25 which Torrent has presented this as how they operate. So we

1 connect up what does Torrent know from the scientists that are
2 in the center, what are the scientists passing on to the
3 people who communicate to the consumers, what are the -- or
4 the customers. And what are the communications to the
5 customers. So what's been on passed on to the communication
6 person and then what that person passes on to customers
7 becomes highly relevant.

8 MR. RAE: And, Your Honor, just to weigh in here,
9 you're not going to see any objections to Mr. Neravetla's
10 testimony as it relates to communications to consumers about
11 the recalls. I don't think we've objected to any designations
12 on that front. And that's not what we're objecting to here.

13 MR. NIGH: Yeah. But my point is, it's not just the
14 communication to customers; it's communication from the
15 scientists to the communication person.

16 MR. RAE: Again, this testimony is not asking about
17 communications from scientists to Mr. Neravetla. It's asking
18 about his present day understanding as he's sitting for this
19 deposition in I believe 2021.

20 MR. NIGH: And he has the knowledge, which is what --
21 whether he gets it from the communication from the internal
22 scientists or he possesses it himself, he's still passing it
23 on.

24 SPECIAL MASTER VANASKIE: Ultimately, I believe this
25 is much ado about nothing. I'm sorry, I know you're arguing

1 it at great length, but this information is going to be before
2 the jury in any event.

3 I'll overrule the objection and allow this question
4 and answer from Mr. Neravetla to come in.

5 MR. NIGH: I would just cite, too, that obviously if
6 the line is drawn, you know, at a -- in terms of what is
7 allowed to be presented on carcinogen and causing cancer, you
8 know, we understand that then, if that line is drawn, we're
9 not going to present this testimony. We've been operating
10 that way for the entire time for all of our designations.

11 SPECIAL MASTER VANASKIE: Exactly. If Judge Bumb
12 draws that line, then this is out. But until that line is
13 drawn, it's in.

14 MR. NIGH: Right.

15 SPECIAL MASTER VANASKIE: I've lost my place.

16 MR. RAE: Your Honor, our next objection begins at
17 page 128, line 23.

18 SPECIAL MASTER VANASKIE: Let me get there. 128?

19 MR. RAE: Correct, Your Honor.

20 SPECIAL MASTER VANASKIE: I've got my notes here.
21 128, line 23, and goes to 130, line 9, according to my notes.

22 MR. RAE: Yes, Your Honor.

23 And the fundamental issue here is that the document
24 that's being asked about here is a consumer -- it's a
25 demand -- it's a notice letter being -- notice and demand

1 letter being sent on behalf of consumers, not third-party
2 purchasers or health insurers of valsartan, notifying Torrent
3 of the potential that those consumers will pursue economic
4 loss claims against Torrent with respect to similar issues to
5 the ones that are being litigated in this trial.

6 And we think introduction of the claims that may or
7 may not exist about consumers is well outside of the scope of
8 what this trial is about. It would be extremely -- it's not
9 relevant and it would be extremely prejudicial to bring before
10 the jury the idea that there may be consumer claims in
11 addition to these third-party claims. And, frankly, I thought
12 that was something that both us and plaintiffs have agreed was
13 not going to be part of this trial.

14 SPECIAL MASTER VANASKIE: Daniel?

15 MR. NIGH: Your Honor, I would agree as long as any
16 sort of argument that there wasn't proper notice given before
17 the claim in terms of some states, it doesn't actually have to
18 be notice given from that specific party to the defendant,
19 just notice of a claim and the facts underlying that claim.

20 So to the extent that we don't have a disagreement
21 that the information can be used for those purposes, we would
22 agree that this would not be designated and shown to the jury.
23 It's more of a legal question.

24 SPECIAL MASTER VANASKIE: Jacob?

25 MR. RAE: Your Honor, notice of claims by consumers

1 is different from notice of claims by health insurers and
2 third-party purchasers. And so even -- like, I'm not sure
3 kind of what agreement Mr. Nigh is looking for here, because
4 this notice would not provide notice of claims by third-party
5 purchasers against Torrent.

6 MR. NIGH: Yeah. In situations where you don't
7 actually have to have the specific -- where it has to be on
8 behalf of a third-party payor, but rather notice that there
9 are potential claims surrounding the substance of this issue,
10 which would be, you know, NDMA in the product and NDEA in the
11 product.

12 You know, I do agree that this shouldn't necessarily
13 be shown to the jury, but we don't want to come back and later
14 the defendants say, well, you didn't designate this so you
15 can't use this for any purpose. That's all.

16 To the extent that we need it to be able to show the
17 judge to establish some sort of dispute that the defendants
18 still have, we would still say that we could show this to the
19 judge.

20 SPECIAL MASTER VANASKIE: If that becomes an issue,
21 you can show that to the judge; but it shouldn't be presented
22 to the jury, at least without more context.

23 So I will sustain the objection.

24 What's your next -- go ahead, Jacob.

25 MR. RAE: Your Honor, I was going to say, I think

1 that's the same issue for 130, line 15 to 23. I just wanted
2 to confirm. This is just another question about the content
3 of that notice letter.

4 SPECIAL MASTER VANASKIE: It is the same issue, and
5 it will be the same ruling.

6 MR. NIGH: Agreed.

7 MR. RAE: And then our only remaining objections for
8 Mr. Neravetla relate to questions on line 140, lines 15 to 23,
9 and then page 141, line 8 to 10.

10 And this is essentially the same issue, just related
11 to a subsequent complaint on behalf of consumers.

12 SPECIAL MASTER VANASKIE: Yeah. Dealt with service
13 of process, et cetera.

14 And this is being introduced for purposes of showing
15 notice, Daniel?

16 MR. NIGH: Hold on one second.

17 Are we talking about 9 to 23?

18 SPECIAL MASTER VANASKIE: Page 140.

19 MR. RAE: Yes, Mr. Nigh, that's what we're looking
20 at.

21 MR. NIGH: Yes. This is the same issue as the
22 previous one.

23 SPECIAL MASTER VANASKIE: Yeah. And it's the same
24 ruling. I'll sustain the objection.

25 And this continues over to page 141, line 10.

1 All right. Are there any other objections for
2 Mr. Neravetla's testimony?

3 MR. RAE: No, Your Honor. That was it for
4 Mr. Neravetla.

5 MR. NIGH: Correct.

6 SPECIAL MASTER VANASKIE: We go to Susan Perry next?

7 MR. NIGH: Yes.

8 MR. RAE: Yes.

9 SPECIAL MASTER VANASKIE: Give me a second. I have
10 her testimony in front of me. I'm looking for her
11 spreadsheet. I have it.

12 MR. NIGH: It's right underneath the one you were
13 just looking at. Kalpesh Patel is in between.

14 SPECIAL MASTER VANASKIE: I see. Okay.

15 MS. SMITH: Excuse me, Judge, this is Loretta.
16 May I intrude for just a second?

17 SPECIAL MASTER VANASKIE: Certainly.

18 MS. SMITH: I have the transcripts of the deponents,
19 but I do not have the Excel spreadsheets.

20 Could someone please send them to me?

21 And just the ones that we are looking at going
22 forward. Thank you.

23 SPECIAL MASTER VANASKIE: Thanks.

24 And this will be on the same spreadsheet as the last
25 one we looked at, Neravetla?

1 MR. NIGH: Yes. Kathryn is sending those right now.

2 SPECIAL MASTER VANASKIE: Thank you.

3 Okay. I'm finally there.

4 I have the first objection for Susan Perry occurring
5 at -- and I could be wrong on this -- page 151. There's also
6 an objection at page 100.

7 Is that still being pursued?

8 MR. RAE: Your Honor, the objection at page 100 was
9 only tied into the counter. And since plaintiffs have
10 withdrawn their objection to the counter, there's no longer a
11 relevant objection there.

12 SPECIAL MASTER VANASKIE: Okay. So am I correct --
13 probably not -- page 151, the first objection, do we need to
14 discuss?

15 MR. RAE: Yes, Your Honor. But we've actually
16 withdrawn our objection to that first question in this
17 segment. So our objection currently begins at 152, line 8 and
18 runs through the two questions and answers through the 153,
19 line 3.

20 SPECIAL MASTER VANASKIE: So the question I have at
21 152, line 8 reads: So your testimony today as a quality
22 assurance personnel for Torrent in the United States, that you
23 did not oversee the quality of the API or the finished dose
24 that were purchased or completed in the India plant.

25 Is that it?

1 MR. RAE: That's the question, Your Honor, yes.

2 SPECIAL MASTER VANASKIE: What's the basis for the
3 objection?

4 MR. RAE: This -- it's a form objection. This
5 mischaracterizes the testimony that the witness had already
6 given. And it's also an unnecessarily argumentative question.
7 And, frankly, Your Honor, the testimony that we haven't
8 objected to at page 153, line 4 to 154, line 7 provides the
9 substantive content that plaintiffs are asking about here
10 without objectionable questioning.

11 SPECIAL MASTER VANASKIE: All right. Daniel?

12 MR. NIGH: It's just foundational information. I
13 think --

14 SPECIAL MASTER VANASKIE: Yeah. It appears to me
15 foundation. I'll overrule the objection.

16 What is your next objection, Jacob?

17 MR. RAE: The next objection is -- it's at page 175.
18 And on page 175, it's questions introducing the document, but
19 we object generally to the use of this document and the
20 questioning about it.

21 And the issue here -- and this is actually
22 testimony -- this relates to an issue where plaintiffs have
23 withdrawn other testimony after we kind of explained our
24 objection when it related to other witnesses, like Dawn Chitty
25 and I think possibly Bernadette Attinger as well.

1 The underlying document in the kind of email that's
2 being raised involves Ms. Perry asking questions about ZHP's
3 amendment with respect to its DMF changes to institute the
4 zinc chloride process, the new process for its API
5 manufacturing.

6 And Ms. Perry asks some questions in the designated
7 testimony -- that's asked about in the designated testimony
8 related to whether or not Torrent has seen results -- there's
9 evidence that ZHP has done additional residual solvent testing
10 with respect to that process change.

11 We think that this line of questioning is irrelevant
12 to the case against Torrent in that Torrent -- everyone agrees
13 Torrent did not use new process API in the United States.
14 This case is not about Torrent's use of new process API, which
15 only took place in other countries. It used old process API.

16 So questions that Ms. Perry is asking about the DMF
17 amendment for new process API are simply irrelevant to this
18 case. And it's going to be very confusing to the jury to see
19 a line of questioning in an email where Torrent is asking
20 questions about ZHP's new process when the case that they're
21 going to hear is about how Torrent used old process and that
22 Torrent did not use new process.

23 SPECIAL MASTER VANASKIE: Daniel?

24 MR. NIGH: Yes, Your Honor. And I apologize. We're
25 going to withdraw -- and I believe it starts at 175, line 5

1 and goes through to line -- or 192, line 22.

2 Is that correct, Jacob?

3 MR. RAE: That is correct, yes.

4 MR. NIGH: Okay. We're withdrawing --

5 SPECIAL MASTER VANASKIE: So withdrawn is 175,
6 lines 5 through page 192, line 22.

7 MR. NIGH: Yes.

8 SPECIAL MASTER VANASKIE: All right. The next I have
9 is page 297, but correct me if I'm wrong on that, Jacob.

10 MR. RAE: That's correct. And it's actually the
11 objection is at 298, line 11 to 23.

12 SPECIAL MASTER VANASKIE: Okay. So tell me, please,
13 the basis for your objection.

14 MR. RAE: Your Honor, the objection here is largely a
15 403 objection that I personally find this line of questioning
16 confusing. I'm not, you know, sure what the relevance of it
17 is or kind of what it's supposed to be conveying to the jury.
18 And I think the jury -- given that I'm confused by it, I would
19 think that the jury would also be confused by it.

20 SPECIAL MASTER VANASKIE: All right. Daniel?

21 MR. NIGH: Hold on. I'm sorry, my computer is
22 freezing as it's loading this. This is through to line 23?

23 SPECIAL MASTER VANASKIE: Yeah. On page 298.

24 MR. RAE: And --

25 MR. NIGH: Yeah. Your Honor, it's a question from a

1 consumer in the US who is asking whether or not the products
2 that Torrent is taking are affected by this recall because
3 they're seeing issues. And this shows that it's not --
4 Torrent is communicating to customers that their product is
5 not affected by this recall.

6 And it's on August 27, 2018, which we find to be
7 highly probative because at this time ZHP has notified Torrent
8 that there is NDMA in their product.

9 So for them to only say, no, your product is not
10 affected by this recall and not supply the full, complete
11 information, which is, well, we actually have received some
12 information that there's NDMA in this product. They leave
13 that out.

14 MR. RAE: Your Honor, we'll withdraw our objection on
15 this line of testimony. Not accepting kind of some of the
16 things that Mr. Nigh is saying about the facts here, but I'm
17 willing to withdraw the objection.

18 SPECIAL MASTER VANASKIE: All right. The objection
19 is withdrawn.

20 And so to be clear, what will come in is page 297,
21 lines 7 through 298, line 23.

22 The next one I have is page 347.

23 MR. RAE: Yes, Your Honor. So our objection here, I
24 think the 403 objection is largely going to be tied to the
25 general causation issues that are in front of Judge Bumb and

1 the scope of discussion of NDMA being a carcinogen that's
2 going to come into this trial. But in addition to that, we
3 think this question is unnecessarily argumentative and
4 mischaracterizes the prior testimony of the witness.

5 And in particular is unnecessarily argumentative,
6 like, in light of the fact that the prior line of questioning
7 where like -- the question kind of implies that the witness
8 has been obstructive in the answers that had come before, and
9 that's simply not the case. And there's prior questions and
10 answers, like the one that comes just before this, where --
11 and two before, that where there's a question about the
12 witness's understanding of the risk associated with
13 nitrosamines. The witness testifies that she's not a
14 physician and doesn't have the medical background to make
15 those decisions.

16 The next question is about whether or not she's aware
17 that it's a potential carcinogen, a genotoxic impurity, does
18 she understand that. And she answers that she understands
19 that above a certain dosage it could be.

20 And then she's asked this argumentative question
21 about essentially the same issue of where kind of this -- the
22 answer is yes, you understand that component, that, again,
23 makes it seem as if she's been obstructive or hasn't been
24 answering the question, when in fact she has been.

25 SPECIAL MASTER VANASKIE: I think you're reading too

1 much into it, Jacob. I will allow this question and answer to
2 be presented.

3 Next I have page 363.

4 MR. RAE: Your Honor, this is -- page 363, there's
5 simply no answer -- there's no question here. They didn't
6 designate the rest of the line of questioning that includes
7 the question. And they didn't designate the answer.

8 SPECIAL MASTER VANASKIE: Daniel, I didn't see a
9 question here.

10 MR. NIGH: There might be a typo. Sorry.

11 SPECIAL MASTER VANASKIE: Oh, okay.

12 MR. NIGH: Let me see if it makes sense later -- 14
13 to 18.

14 Your Honor, we'll withdraw 363:14 through 18.

15 SPECIAL MASTER VANASKIE: Okay. I think this takes
16 us to page 364, line 17 to page 366, line 9.

17 MR. RAE: Correct, Your Honor.

18 And our objection here begins at page 365, line 13.
19 I think we erroneously indicated that it began at line 12 on
20 the spreadsheet, but it begins at 365, line 13 and then runs
21 through the end of this designation at page 366, line 16.

22 SPECIAL MASTER VANASKIE: Okay.

23 MR. RAE: And our objection here is that this is a
24 confusing line of questioning because the line of questioning
25 doesn't establish or explain what a field alert report is.

1 And so the plaintiffs are kind of -- there are a couple of
2 different steps in a recall process, and this line of
3 questioning kind of skips over the recall steps and jumps to
4 the field alert steps, and because of that, makes it seem like
5 the recall is happening later than it actually happened.

6 SPECIAL MASTER VANASKIE: Daniel?

7 MR. NIGH: Well, I think that the purpose of it is
8 that it's actually the field alert isn't happening until
9 later, so it's the inverse of what Jacob just described. You
10 know, we can see that -- so any sort of field alert isn't
11 happening here until August 24, even though they're made aware
12 of impurities prior to when the FDA found them on August 16th.
13 It's relevant for that --

14 SPECIAL MASTER VANASKIE: Any response, Jacob?

15 MR. RAE: Again, I think that -- with absent any
16 explanation or questioning of this witness about the
17 difference between field alerts and recall timing, this line
18 of questioning is going to be confusing to the jury.

19 SPECIAL MASTER VANASKIE: I think that can be
20 clarified through other evidence. I'll overrule the
21 objection.

22 MR. RAE: Your Honor, I have one other very, very
23 small objection --

24 SPECIAL MASTER VANASKIE: Okay.

25 MR. RAE: -- on a 403 basis and foundation basis

1 within this line of questioning, which is on page 366, line 4.

2 The question that begins on line 3 is: Okay. But

3 Torrent was actually aware prior to or on October 16 --

4 SPECIAL MASTER VANASKIE: August 16.

5 MR. RAE: -- on August 16th -- thank you, Your

6 Honor -- that the FDA found impurities in the Torrent

7 valsartan. Correct?

8 And our objection here is just to the three words

9 "prior to or," where the witness -- where the counsel begins
10 to ask the question from a "prior to" framing and then pivots
11 to "on August 16th."

12 And if kind of "prior to" and "or" were excised from
13 this question in the clip that's played, so that it would read
14 and be presented to the jury as "but Torrent was actually
15 aware on August 16th," we don't think that there would be any
16 confusion. I think that's the question that the witness is
17 answering and understood themselves to be answering.

18 And so kind of that would alleviate any prejudice and
19 compound issues or confusion issues from the way in which this
20 question was originally phrased and the correction that took
21 place in the middle of it.

22 SPECIAL MASTER VANASKIE: So it would read: But
23 Torrent was actually aware on August 16th?

24 MR. RAE: Correct, Your Honor. That's what we would
25 be asking for.

1 MR. NIGH: I believe we can splice that and we can do
2 that. To the extent we can, we agree.

3 SPECIAL MASTER VANASKIE: All right.

4 MR. NIGH: We would take out "prior to or."

5 SPECIAL MASTER VANASKIE: Very well.

6 Does that conclude Ms. Perry?

7 MR. RAE: Yes, Your Honor, it does.

8 SPECIAL MASTER VANASKIE: And we now move to Kalpesh
9 Patel?

10 MR. NIGH: Yes, Your Honor.

11 SPECIAL MASTER VANASKIE: Give me a second.

12 Let's take a five-minute break while I pull up these
13 documents, just till 11:45. All right?

14 MR. NIGH: Okay.

15 SPECIAL MASTER VANASKIE: Thank you.

16 (Recess at 11:39 a.m. until 11:45 a.m.)

17 SPECIAL MASTER VANASKIE: Okay. I am back.

18 We're picking up with Kalpesh Patel. And I have the
19 first area at page 38, line 21.

20 Is that accurate?

21 MR. RAE: That's correct, Your Honor.

22 SPECIAL MASTER VANASKIE: So at page 38, line 21, the
23 question is: Okay. So you've had some regulatory affairs
24 experience with the US regulatory agency, which is commonly
25 known as the FDA.

1 And you're objecting to that question, Jacob?

2 MR. RAE: Your Honor, I think our objections here --
3 yes, but there's kind of a broader context to our objection
4 here, which is the purpose of this line of questioning appears
5 to be plaintiffs trying to kind of qualify Mr. Patel as some
6 form of regulatory affairs or FDA communication or FDA
7 regulatory requirement expert so that they can then ask him
8 questions about the regulatory process as it relates to
9 valsartan.

10 And so we think that this line of questioning is
11 unfairly prejudicial in the context in which they're going to
12 be using it later in the deposition, and also because, as is
13 clear in our counter-designation, which I understand
14 plaintiffs are not objecting to, Mr. Patel's experience does
15 not relate to these issues with respect to valsartan.

16 SPECIAL MASTER VANASKIE: Daniel?

17 MR. NIGH: Your Honor, I think just to kind of set
18 the stage, Kalpesh Patel is one of the senior management folks
19 at Torrent. So this idea that once we start getting into
20 objections relating to his qualifications, we're going to keep
21 coming back over and over.

22 And this just shows one of the facets as which he is
23 involved in many assets or many different issues at the
24 company. He's the general manager of quality. He has a PhD
25 for the general requirement of GMP for pharmaceutical

1 excipients and API, where his focus is to compile the various
2 GMP guidelines and maintain compliance. That's further --

3 SPECIAL MASTER VANASKIE: Slow down a little bit,
4 Daniel. Slow down a little bit.

5 MR. NIGH: Sure. Sorry.

6 SPECIAL MASTER VANASKIE: Okay.

7 MR. NIGH: At Torrent he's responsible for research
8 and development, quality assurance and support to quality
9 functions of subsidiaries. I mean, he has -- he's very
10 multifunctional in the company, and he has a wider range of
11 knowledge.

12 The fact that he possesses that knowledge is
13 certainly, you know, something we can speak to, because this
14 is the sort of person who has multifacet -- or multifunction
15 knowledge, you know, which ultimately, it's obvious in his
16 capacity as -- you know, he uses that in his day to day at
17 Torrent.

18 SPECIAL MASTER VANASKIE: Jacob?

19 MR. RAE: Your Honor, I think I've explained the
20 basis for our objection here. It's mostly about if the
21 relevance of his experience communicating with the FDA and
22 dealing with regulatory issues regarding other products. And
23 that's not relevant to the issues in this case, which are
24 about valsartan.

25 SPECIAL MASTER VANASKIE: I think it's relevant to

1 assessing this witness's credibility, his background, so I
2 will allow it.

3 I think that takes us now to page 46.

4 MR. RAE: Yes, Your Honor.

5 SPECIAL MASTER VANASKIE: And you have a counter on
6 page 46 as well.

7 MR. RAE: Correct. And I believe there was no
8 objection to our counter, which just completes the question
9 asked.

10 SPECIAL MASTER VANASKIE: Completes the question,
11 yes.

12 So what's the objection to the question at page 46,
13 starting at line 21, and then the answer on page 47 at line 7?

14 MR. RAE: So our objection here gets back to the fact
15 that Mr. Patel is not in fact an expert or qualified to give
16 opinion testimony on these issues and that this -- they're
17 asking him to provide essentially a lay witness opinion on the
18 general question of what is required from a testing
19 perspective for finished dose manufacturers after a product is
20 on the market.

21 And this question and its answer are particularly
22 problematic, because plaintiffs' own CGMP expert provides
23 opinions that are in conflict with the question that's being
24 asked here and the testimony that's being given, which is that
25 Mr. Russ testifies in his report -- opines in his report, and

1 I assume will testify, to the fact that finished dose
2 manufacturers do not have an ongoing obligation to conduct
3 full testing of their products.

4 Now, that's not really relevant here, because Torrent
5 in fact did fully test all of the API it was getting from ZHP
6 with respect to the valsartan API.

7 But it highlights why it's a problem to ask this
8 witness to provide this sort of expert opinion testimony,
9 where his opinions are speaking to a higher standard than what
10 plaintiffs' own expert is going to articulate applies here,
11 and, therefore, is prejudicial to Torrent and is likely to
12 confuse the jury because they're going to hear different
13 articulations of what the regulatory standards here are,
14 despite the fact that on this issue of the scope of testing
15 that's required under CGMP, I think both plaintiffs' expert
16 Mr. Russ and Torrent's expert Dr. Nagaich generally agree on
17 the scope of what is required from a testing perspective.

18 And this is just an issue that should come in through
19 the experts, not through lay witness testimony being elicited
20 through Mr. Patel.

21 SPECIAL MASTER VANASKIE: Daniel?

22 MR. NIGH: Your Honor, I think a lay witness is
23 really something else. But here we asked him ongoing duty of
24 Torrent to continue to test the batches of that product to
25 ensure quality. Kalpesh Patel is the general manager of

1 quality. So for him to be able to answer that -- I mean,
2 general manager is the highest person, you know. You've got
3 Kalpesh Patel and you've Sushil Jaiswal have both held that
4 position.

5 On top of that, his PhD is general requirement of GMP
6 for pharmaceutical excipients and API. I mean, there's not a
7 better person to ask this question.

8 So whether or not what -- whatever the experts are
9 going to do with this testimony really is irrelevant, because
10 the first question is, can he testify to this information.
11 Yes, he can.

12 What happens with the experts thereafter is -- there
13 are multiple things that could occur with them. And we get
14 this -- how we want to present that information.

15 SPECIAL MASTER VANASKIE: I think this is proper.
16 I'll overrule the objection.

17 The next area I have is on page 67.

18 MR. RAE: I think -- unless Mr. Nigh is going to
19 correct me, I think we've kind of agreed that the -- any
20 testimony on 67 is coming in and that the next place where
21 there is an objection is on page 130.

22 SPECIAL MASTER VANASKIE: Okay. Good.

23 MR. NIGH: I agree.

24 SPECIAL MASTER VANASKIE: Let's go to 130.

25 And this then goes to Mr. Patel's background with

1 respect to FDA regulations.

2 MR. RAE: Yes. And, Your Honor, I assume your prior
3 rulings are going to apply here and you're going to overrule
4 the objection.

5 SPECIAL MASTER VANASKIE: I am going to overrule the
6 objections. I think this is -- I don't see a basis for
7 disallowing it.

8 Do we go to page 151 now?

9 MR. NIGH: Yes, Your Honor.

10 SPECIAL MASTER VANASKIE: A counter-designation and a
11 designation.

12 Does allowing the counter-designation inobviate a
13 ruling on the designation itself?

14 MR. RAE: Your Honor, for our objection at 151,
15 line 2 to 9, allowing the counter-designation would obviate
16 the need for a ruling, yes.

17 We would still have an objection on page 152, line 8
18 to 153, line 13.

19 MR. NIGH: Your Honor, we did have a counter to the
20 counter on this one, which is 151:21 to 152:7.

21 SPECIAL MASTER VANASKIE: Right.

22 MR. RAE: Your Honor, we have no objection to that
23 testimony coming in.

24 SPECIAL MASTER VANASKIE: So can we make it clear on
25 the record what is in dispute here?

1 MR. RAE: Your Honor, my understanding is that 151:2
2 to 152:7 the parties have just now agreed will come in in its
3 entirety.

4 SPECIAL MASTER VANASKIE: All right.

5 MR. NIGH: I agree.

6 SPECIAL MASTER VANASKIE: So what is in dispute on
7 page 152? Anything?

8 MR. RAE: Yes, Your Honor. We have a foundation and
9 701 objection to the testimony at 152:8 to -- 152, line 8 to
10 152, line 21.

11 SPECIAL MASTER VANASKIE: 153, line 21. No, 152 line
12 21. Okay.

13 MR. RAE: And then we also have an objection to the
14 next question and answer from 152, line 22 to 153, line 13,
15 which would be the same objections but also a 403 objection.

16 I think the foundation objection, because it would
17 apply to everything, and the 701 objection are the places to
18 start.

19 I think your prior rulings on our 701 objections are
20 likely to apply here as well, so I just want to focus on the
21 602 foundation objection, which is the witness in our
22 counter-designation at 152, line 18 to 20, testifies that for
23 this particular guidance, he's not sure that he's seen it
24 before. And so we think that following up and asking him --
25 leaving out the content of that guidance from the FDA and

1 asking did I read that correctly is improper, that this is --
2 you can't kind of establish the witness does not know or have
3 personal knowledge or familiarity with the document and then
4 ask them to read that document into the record.

5 THE COURT: So why do you need that, Daniel? You're
6 asking whether the witness -- whether you read correctly from
7 a certain document. The witness says: Yeah, you read it
8 correctly. I don't understand why that's appropriate
9 examination.

10 MR. NIGH: Well, the next question is we asked him
11 about the information contained within that document, and he
12 agrees with the information contained within that document.

13 So you know, he says he's aware with good
14 manufacturing practice that the FDA issues generally, he
15 reviews these in his position as head of quality -- sorry,
16 general manager of quality. You know, these are all sorts of
17 things that he should be aware of, and so we can use that
18 document for that purpose in his role in that capacity.

19 And then on top of that, we ask him the information
20 contained within that, and he gives a full explanation, you
21 know, that shows -- do you agree that consumers, once a drug
22 is commercialized, expect the product that's being distributed
23 to both safe and effective."

24 And he gives a full answer on that topic as well. We
25 don't think that there's anything that can't be discussed

1 there.

2 The foundation is merely the fact of his job, he's --
3 his title, what he does, and the fact that he's aware of these
4 guidances generally.

5 SPECIAL MASTER VANASKIE: Why isn't it sufficient,
6 Daniel, to simply ask the question that starts on line 22 of
7 page 152 and then the answer --

8 MR. NIGH: I do agree that that gives most of the
9 information, but I also believe that we're allowed to ask the
10 information -- we're allowed to read the document itself,
11 based on his capacity, you know, that these are the sorts of
12 documents that he should be aware of.

13 So foundationally, which I think is the question
14 here, he has the capacity or he should have the ability to be
15 able to speak to these issues based on his job function at the
16 company.

17 SPECIAL MASTER VANASKIE: Jacob?

18 MR. RAE: Your Honor, I think Your Honor is correct
19 that there's no need for the reading of the document to ask
20 the second question.

21 For record purposes, I want to preserve that we have
22 an objection to that second question because we think it's
23 asking Mr. Patel to provide an opinion on what consumer
24 expectations are, which is not an opinion that he's in a
25 position to apply. He shouldn't be asked to speculate about

1 the state of mind of consumers.

2 However, I think Your Honor has previously addressed
3 similar objections that we had and overruled them, so I don't
4 know that we have to go through that discussion again. I just
5 want to make it -- articulate what our additional objection
6 was to that testimony.

7 SPECIAL MASTER VANASKIE: Yeah. I'm going to sustain
8 the objection at 152, lines 8 through -- and the answer
9 continues -- let me start all over again.

10 Page 152, line 8 through line 21 are out.

11 I just -- I have trouble with reading something and
12 the question is, did I read that correctly? I'm not sure
13 there's anything substantive there. I understand it can be
14 foundational, but I don't think -- or introductory, but I
15 don't think it's necessary.

16 But I'll overrule the objection to the question that
17 begins on page 152, line 22 and allow the answer at page 153,
18 lines 5 through 13.

19 MR. NIGH: Thank you, Your Honor.

20 SPECIAL MASTER VANASKIE: Now, the next one I have in
21 my notes is page 162.

22 MR. RAE: I think this is in -- from 169, line 19 to
23 page 162, line 23 is a counter that plaintiffs are objecting
24 to.

25 SPECIAL MASTER VANASKIE: Is a counter.

1 Are you objecting to that counter, Daniel?

2 MR. NIGH: Yes, Your Honor. First off, it's not --
3 this is one of the few that's not responsive to the
4 information that we've designated. And it's actually not even
5 responsive to the question. When he starts going to open part
6 of the DMF and closed part of the DMF, we didn't ask anything
7 related to any of that.

8 SPECIAL MASTER VANASKIE: Go ahead, Jacob.

9 MR. RAE: Your Honor, this is -- the questioning both
10 before and after our counter-designation is asking Torrent
11 about the requirements and its obligations to oversee and make
12 sure that its API supplier is complying with CGMP.

13 So I think the most pertinent question here is the
14 one at page 156, line 8 to 17, where the question is: Right.
15 And these are the same GMPs that we discussed before that
16 you've been involved in the course of your career with Torrent
17 to make sure that both the API supplier and Torrent are
18 compliant with?

19 And so the counter here goes to the issue of what
20 Torrent is capable of doing with respect to ensuring
21 compliance by an API supplier and what the limits and bounds
22 of that capacity are.

23 It's necessary context so that the jury isn't just
24 hearing kind of a curtailed version of Torrent generally
25 having an obligation to oversee its API supplier without

1 hearing that there are certain limits that exist as a
2 practical matter that everyone in the industry acknowledges,
3 including the FDA, as to what a finished dose manufacturer is
4 supposed to be doing with respect to an API supplier and that
5 there -- the lack of access to certain parts of the DMF means
6 that the responsibilities with respect to CGMP compliance for
7 those parts of the process that the finished dose manufacturer
8 isn't aware of falls on the API supplier.

9 MR. NIGH: Yeah, but -- you know, first off, I don't
10 think that that's responsive. But on top of that, the
11 question that he interjects this into, it's not even
12 responsive to that question. Like, we didn't designate that
13 question. They designated it just to try to get this
14 information in. It's not even responsive to that question.

15 SPECIAL MASTER VANASKIE: How is this responsive to
16 the matters to which he was testifying?

17 MR. RAE: Your Honor, the question right after our
18 counter-designation is: Part of your validating or qualifying
19 of an API supplier is making sure they're complying with the
20 good manufacturing processes, true?

21 And the answer is: Yes.

22 And the context for that question and answer is the
23 explanation that Mr. Patel just gave about the limitations
24 that exist on the knowledge that Torrent has of the
25 manufacturing process and the route of synthesis for API and

1 how that plays into the scope of supervision and
2 responsibilities that Torrent has with respect to that
3 process, which is the very process that is at issue in this
4 case.

5 So it's extremely relevant to this case for the jury
6 to understand that there were parts of ZHP's DMF, information
7 about its route of synthesis that Torrent did not have and
8 that finished dose manufacturers, as a general matter, do not
9 have.

10 MR. NIGH: Your Honor, I would say the -- I guess the
11 one part that just looks somewhat responsive is the word
12 "but." "All right, but."

13 So, you know, in terms of that, if that's the
14 argument, then we would just withdraw 162, line 24 to 163,
15 line 4, because I think it's repetitive.

16 But I think at that point, we're not responsive to
17 anything on this counter.

18 SPECIAL MASTER VANASKIE: So are you withdrawing
19 162:24 to 163:4?

20 MR. NIGH: Right. If that takes care of the counter,
21 we are.

22 SPECIAL MASTER VANASKIE: Does that take care of the
23 counter, Jacob?

24 MR. RAE: As I said at the beginning, I think that
25 this counter is also relevant to the questioning at 155, line

1 19 to 156:17.

2 But we will -- we'll abide by any ruling Your Honor
3 makes on this issue, obviously.

4 SPECIAL MASTER VANASKIE: Obviously. I don't want to
5 force the ruling.

6 When I went through this, my notes were allow both
7 the designation on 163, line 24 to 164, line 4 and the counter
8 at 161, lines 19 to 162, line 23.

9 I'm going to stick with that ruling and allow both.

10 MR. NIGH: Your Honor, just to make it clear, it's
11 162, line 24 to 163, line 4.

12 But if we're withdrawing that, does that withdraw the
13 counter?

14 SPECIAL MASTER VANASKIE: Well, that's up to Jacob.
15 I'm not -- are you withdrawing the counter?

16 MR. NIGH: Otherwise -- the reason I say that is,
17 otherwise I don't see anything in 24 other than the words "all
18 right, but" that make that information responsive to anything.
19 And it's just -- the only reason it's responsive in that
20 question is because the next statement he's saying "but" and
21 pivoting to another topic. That's all that makes it
22 responsive.

23 And that information that's just thrown in there
24 isn't responsive even to the question that's asked that they
25 want to designate.

1 SPECIAL MASTER VANASKIE: All right. Let me reverse
2 myself then.

3 So if you withdraw 162, lines 24 to 163, line 4, I
4 will sustain your objection to the counter-designation at 161,
5 line 19 to 162, line 23.

6 MR. NIGH: Okay.

7 SPECIAL MASTER VANASKIE: So are you withdrawing
8 that?

9 MR. NIGH: Yes, Your Honor.

10 SPECIAL MASTER VANASKIE: All right. So the
11 objection is sustained and nothing is coming in from page 162,
12 line 19 through 163, line 4. 161, line 19 --

13 MR. NIGH: Yes.

14 SPECIAL MASTER VANASKIE: -- through 163, line 4.

15 MR. NIGH: Yes.

16 MR. RAE: Yes.

17 SPECIAL MASTER VANASKIE: I think that takes us to
18 211, unless I'm missing something.

19 MR. RAE: That's right, Your Honor. And our
20 objection here is I think a familiar one by now, which is this
21 is attorney commentary that doesn't designate an actual
22 question or an answer.

23 MR. NIGH: The first part is introducing the
24 document, so pulling up 0357. The second part is -- which I
25 think is 211:11 to 23 --

1 SPECIAL MASTER VANASKIE: Yes.

2 MR. NIGH: Your Honor, we'll withdraw these two.

3 SPECIAL MASTER VANASKIE: Okay. They're withdrawn.

4 That will take us to 228 now.

5 MR. NIGH: Yeah. I should say we may still need the
6 document itself, the 211:5 to 7, but I just need to make sure
7 if they're the same document.

8 MR. RAE: I'm going to ask Mr. Nigh if you're aware
9 if the question on page 237 is asking about the same document;
10 because if it is, then we will withdrawn our objection to the
11 introduction of the document.

12 MR. NIGH: I think it is. So we need to keep the
13 211:5 to 7, but we withdraw 211, lines 11 to 23.

14 SPECIAL MASTER VANASKIE: All right.

15 MR. NIGH: And to the extent that is not the
16 questions we find aren't responsive, we would then just
17 withdraw that, obviously, because we don't want to mislead
18 with the wrong document, but I'm pretty sure it is.

19 SPECIAL MASTER VANASKIE: Okay. Does that take us
20 now to page 228?

21 MR. RAE: Yes, Your Honor. And our objection here is
22 that this is confusing and a potentially prejudicial line of
23 questioning in that kind of we jump straight to questions
24 about what is done with genotoxic evaluations, but no one is
25 telling the jury what a genotoxic evaluation here is.

1 Plaintiffs haven't designated any testimony explaining what a
2 genotoxic evaluation is, even though this witness did testify
3 to that. And I don't believe that there's any other testimony
4 that they've designated from any other Torrent witness
5 regarding genotoxic evaluations.

6 So in that context, I think this is an incredibly
7 confusing line of questioning, to talk about what's being done
8 with genotoxic evaluations when it's not established what they
9 are or what their purpose in the process is, when they're
10 used, when they're not used.

11 MR. NIGH: Your Honor, the only relevance of this
12 question is the genotoxic evaluation goes to the quality
13 assurance department. And that's really all we need. We can
14 have other experts who, you know, testify on this issue, on
15 these are the people who have should have done X, Y, and Z
16 within the company.

17 SPECIAL MASTER VANASKIE: Yes, I don't see this as
18 being unduly prejudicial. I'll overrule the objection.

19 That should take us to 237.

20 MR. RAE: Yes, Your Honor.

21 And I think our objection at 237:8 to 17 is very
22 similar to the prior one, that plaintiffs are not asking any
23 questions or designating any testimony that provides the jury
24 with any context about what a genotoxic evaluation is, and
25 that makes this entire line of questioning confusing. And

1 it's less -- I think the potential for that confusion creates
2 potential prejudice -- unfair prejudice to Torrent because
3 it's hard to -- because what a genotoxic evaluation is, is not
4 being established.

5 SPECIAL MASTER VANASKIE: And your response, Daniel?

6 MR. NIGH: It doesn't have to be established with
7 this witness. As we've seen, you know, the underlying what is
8 a genotoxic evaluation, you know, that's the sort of issues
9 that can be established through other witnesses, other
10 experts.

11 He had spoken to he is the person responsible for
12 genotoxic evaluations, and now we're showing him a document
13 pertaining to genotoxic evaluations.

14 SPECIAL MASTER VANASKIE: Yes, I think it can be
15 established through other witnesses as well. So I will allow
16 it, overrule the objection.

17 MR. RAE: Your Honor, just because we're dealing with
18 these issues in advance of trial, obviously, kind of, I just
19 want to confirm and ask Mr. Nigh like -- he may not be willing
20 to answer this question, but what other witness is going to
21 establish what a genotoxic evaluation is? Because I'm not
22 aware of where else that would come in except through the
23 testimony that Mr. Patel has given on that topic that you guys
24 are not designating.

25 MR. NIGH: In case-in-chief, the other witnesses that

1 could talk about a genotoxic evaluation would be Dr. Najafi,
2 it would be Dr. Russ, Dr. Plunkett and Dr. Hecht.

3 SPECIAL MASTER VANASKIE: All right. Now I have us
4 up to page 328, line 14 to 24.

5 MR. RAE: Yes, Your Honor.

6 SPECIAL MASTER VANASKIE: What's the basis here?

7 MR. RAE: Your Honor, I think this is the same issue
8 that Your Honor has already addressed with respect to
9 genotoxic evaluations.

10 SPECIAL MASTER VANASKIE: So the objection is
11 overruled, and it will come in.

12 Does that complete this witness then, Kalpesh Patel?

13 MR. NIGH: Yes, Your Honor.

14 MR. RAE: Yes, Your Honor.

15 MR. NIGH: Your Honor, that leaves us with Paras
16 Sheth.

17 SPECIAL MASTER VANASKIE: Right.

18 MR. NIGH: There's not much, but I don't think we can
19 get it done in five minutes.

20 SPECIAL MASTER VANASKIE: Let me find it first.

21 MR. NIGH: Okay.

22 MR. RAE: Your Honor, I would agree with Mr. Nigh
23 that if we had 15 minutes, that might be sufficient, but five
24 minutes is probably cutting things a little bit too close for
25 this witness.

1 SPECIAL MASTER VANASKIE: Ann Marie, are you able to
2 go for another 15 minutes?

3 MR. RAE: Your Honor --

4 SPECIAL MASTER VANASKIE: Are you all okay? You have
5 to go, you have a doctor's appointment.

6 MR. NIGH: I have to go. I have a doctor's
7 appointment is the problem.

8 SPECIAL MASTER VANASKIE: Yeah. I'm sorry about
9 that.

10 MR. NIGH: It's cutting it so close.

11 SPECIAL MASTER VANASKIE: Will you be back?

12 MR. NIGH: I will be. Do we have other witnesses?
13 Because, you know, the only problem is doctor's appointments
14 are sometimes --

15 SPECIAL MASTER VANASKIE: I had it this morning.

16 MR. NIGH: You never know exactly how long they might
17 go. That's part of the problem.

18 SPECIAL MASTER VANASKIE: We do have other witnesses,
19 but not Torrent witnesses.

20 Am I right on that?

21 MR. RAE: Yes. I think -- my understanding is that
22 there are several -- I don't know the exact number, but I
23 think like three to four Teva witnesses --

24 SPECIAL MASTER VANASKIE: Correct.

25 MR. RAE: -- that we need to work through.

1 So I wonder if the best plan is for us to make kind
2 of a tentative plan now for when we would come back to this if
3 Mr. Nigh is not back by the time the Teva process is done.

4 And if he is back, then we will get it done today and
5 we'll be done.

6 SPECIAL MASTER VANASKIE: Yes. Do we have anybody on
7 for Teva? I don't see anybody.

8 MR. STANOCH: Yes, Your Honor. For plaintiff, David
9 Stanoch. I think Ms. Lockard and Mr. Harkins have been on.

10 SPECIAL MASTER VANASKIE: They're here as well?

11 MS. LOCKARD: Yes.

12 SPECIAL MASTER VANASKIE: Okay. I'm only seeing one
13 page. Thank you.

14 So why don't we -- would it be all right if we took a
15 break for lunch right now? We'll pick up at 1:00 Eastern
16 time, if that's okay. That's only 45 minutes.

17 Is that all right?

18 MR. STANOCH: Fine for plaintiffs.

19 MS. LOCKARD: Sure.

20 SPECIAL MASTER VANASKIE: Okay. And so we'll pick up
21 at 1:00 with -- yes, I'm sorry, go ahead.

22 MR. NIGH: I should say, if I were estimating, I
23 would think it would be about 2:30 to 3:00 Eastern that I
24 would be back. But again, there's some uncertainty in that.

25 SPECIAL MASTER VANASKIE: All right. Well, we did

1 set aside time for tomorrow as well --

2 MR. NIGH: I may be wrong.

3 SPECIAL MASTER VANASKIE: -- so if it doesn't work
4 out today --

5 MR. NIGH: Jacob may have had a conflict with that.

6 If Teva has enough witness and taking an hour break,
7 we might -- ours will probably only last 10 to 15 minutes. I
8 think Jacob is right.

9 SPECIAL MASTER VANASKIE: All right. Let's hope we
10 can get them all in today.

11 Go ahead, Jacob.

12 MR. RAE: I was just going to say, if we end up
13 needing to address Torrent witnesses tomorrow, I think we
14 reserved time starting at 10:00 a.m. And I have a medical
15 appointment that might cause 10:00 a.m. to be a little bit
16 tight for me in the morning, so if we could start at -- if we
17 need to do Torrent tomorrow, if we can start at 10:30 instead
18 of 10:00 a.m., that would alleviate any conflict on my end.

19 SPECIAL MASTER VANASKIE: I think we can on our end.
20 So tomorrow we wouldn't start any earlier than 10:30, if we
21 need tomorrow. Hopefully, we won't need it. All right?

22 MR. NIGH: Okay. Thank you, Your Honor.

23 SPECIAL MASTER VANASKIE: Let's take a break until
24 1:00.

25 MS. LOCKARD: Your Honor, may I ask, just to make

1 sure I have my tech lined up, do you have any preferred order
2 in how we present the Teva witnesses?

3 SPECIAL MASTER VANASKIE: Let me ask, do you have a
4 preferred order?

5 MS. LOCKARD: Not necessarily. There's one that's
6 very short, it's just six rows, and then the other two are
7 maybe 30 and 60 rows roughly.

8 SPECIAL MASTER VANASKIE: Let's take the short
9 witness first.

10 MS. LOCKARD: Okay.

11 SPECIAL MASTER VANASKIE: And then we'll go from
12 there. All right?

13 MS. LOCKARD: All right. Sounds good. See you at
14 1:00.

15 SPECIAL MASTER VANASKIE: All right. See you at
16 1:00. Bye-bye.

17 (Recess at 12:21 p.m. until 1:00 p.m.)

18 SPECIAL MASTER VANASKIE: We are starting right on
19 time, so that's a little unusual for me.

20 Let's take care of Michelle Osmian. That's what our
21 intention was all along.

22 So the first objection as I understand it or first
23 area that we have to address is on page 98, line 21 to page
24 101, line 2.

25 MR. HARKINS: Your Honor, the objection here is

1 pretty specific and it is similar to the limited objection
2 that I think we're making for the next several designations.

3 SPECIAL MASTER VANASKIE: Correct.

4 MR. HARKINS: We are objecting only to the question
5 and response at 100, line 2 to 9. And to put that in context,
6 the discussion beginning on page 98:21, where counsel is
7 asking about the content of the generic products purchase
8 agreement and then is asking the witness to confirm statements
9 that are made within and under which sections of that
10 agreement we don't think are objectionable and we think are
11 within the scope of this witness's testimony and what she's
12 been designated to provide.

13 It's the question where rather than confirming the
14 content of the agreement at this question beginning at line 2
15 on page 100, the question now is saying, it states that Teva
16 is representing and warranting to the customer that the
17 product will not be adulterated and misbranded rather than
18 confirming the warranties therein.

19 We don't have any issue with the content of the
20 document coming in through this witness's testimony. It's a
21 few examples throughout the next couple of pages of
22 designations where we think it strays too close to asking this
23 witness to provide a legal conclusion. And that's our
24 objection to that testimony.

25 SPECIAL MASTER VANASKIE: All right. David?

1 MR. STANOCH: Thank you, Judge.

2 Ms. Osmian was a designated 30(b)(6) witness, Your
3 Honor, on topics including oral and written communications
4 with customers and downstream entities regarding quality,
5 purity, et cetera, and also specifically on Teva's oral and
6 written statements defined to include representations and
7 warranties to finished dose manufacturers, wholesalers,
8 resalers and consumers with regards to the contents and purity
9 of Teva's finished dose.

10 So it's right within the scope of these unobjected-to
11 negotiated topics. There's no objection at the time. To ask
12 this witness, who was prepped on these very questions, to
13 speak on behalf of Teva of what representations and warranties
14 or statements were being conveyed to Teva's customers, in this
15 instance, a retail pharmacy that's purchasing valsartan, we
16 think it's an appropriate question -- line of questioning, and
17 we can certainly ask that prepared corporate witness more than
18 just could you confirm the words on this written agreement
19 page. In fact, she had no problem, Your Honor will see, in
20 answering the question that Mr. Harkins is objecting to, and
21 it was asked and answered without any objection whatsoever.

22 MR. HARKINS: Your Honor, I don't know if you want my
23 full responses. I'm certainly happy to limit it, as you
24 please.

25 SPECIAL MASTER VANASKIE: Go ahead.

1 MR. HARKINS: We think that there's a clear
2 difference in the question beginning at line 2 to 9 as
3 compared to the other unobjectionable statements where this
4 witness is being asked, are these representations and
5 warranties contained in the contract, we've not objected. But
6 where counsel is sort of implying a legal conclusion with
7 their question by saying, Teva is representing and warranting
8 to the customer that the product will not be adulterated, and
9 the witness's answer is a little unclear, because it's saying
10 this is essentially what it says here, yes, but she is clearly
11 not qualified to opine on or provide testimony about whether
12 this is Teva representing and warranting to the customer.
13 Those are very central issues in the case.

14 The factual record of what these documents say is
15 appropriate. It's already been brought in through this
16 witness in her other testimony, which we don't think is
17 objectionable, but there are a few questions in here where we
18 think it strays over the line and is asking this witness for a
19 legal conclusion.

20 MR. STANOCH: May I, Your Honor?

21 SPECIAL MASTER VANASKIE: David, what was the witness
22 designated for? What was the topic?

23 MR. STANOCH: Your Honor, I think the topic goes
24 exactly to Mr. Harkins -- what I am hearing now is really a
25 legal conclusion, which I disagree with.

1 This witness was designated on a number of topics
2 including, and I will quote, Teva's oral and written
3 statements, defined to include representations and warranties
4 to finished dose manufacturers, wholesalers, retailers and
5 consumers with regard to the contents and purity of Teva's
6 finished dose, end quote.

7 The actual topic that was agreed to and entered by
8 Judge Schneider that she was designated on, Judge, is defined
9 specifically as representation and warranties. And we're not
10 trying to get into some legal conclusion or anything else, but
11 that was literally the topic. And I used those exact words in
12 my question. And she was obviously prepared, because she
13 answered. And I think I even shared these documents with Teva
14 ahead of time just to make sure this questioning was as
15 concise as possible.

16 So I don't think we're asking for a legal conclusion.
17 I don't think the jury will be confused. There's been no
18 argument by any defendant that the words "representation" and
19 "warranty" and "statements" is going to be prejudicial or
20 misleading. In fact, it would be the other way to us
21 prejudicial, Judge, because this was the very topic we agreed
22 upon that she'd be able to talk about, and I used those exact
23 words.

24 SPECIAL MASTER VANASKIE: All right. I will overrule
25 the objection. Although I agree with you, Steve, that it's a

1 bit unclear, the answer does muddle it, because the answer to
2 the question is "that is essentially what it says or yes."

3 But I will overrule the objection and allow it to
4 come in.

5 MR. HARKINS: Your Honor, I think that will
6 probably -- that may very well inform the next objection at
7 101, line 12 to 101:18 --

8 SPECIAL MASTER VANASKIE: Yes.

9 MR. HARKINS: -- which, again, while we don't object
10 to this, but simply to maintain it for the record, our concern
11 with these are that rather than this witness demonstrating and
12 being presented to document what the representations and
13 warranties are, we feel that this, like a few other questions,
14 could be presented to the jury as this witness providing a
15 legal conclusion that these are representations and warranties
16 which they are going to be asked to decide on as the ultimate
17 issue in this case with respect to plaintiffs' express
18 warranty claim.

19 But, again, I understand Your Honor's ruling with the
20 prior objection as well.

21 SPECIAL MASTER VANASKIE: Same ruling.

22 So the testimony at page 101, lines 12 through 18 can
23 come in.

24 Now we're at page 125.

25 MR. HARKINS: I --

1 MR. STANOCH: I won't interrupt Mr. Harkins, Judge,
2 but this is the same type of issues on just one different type
3 of contract between Teva and a different downstream customer.

4 MR. HARKINS: Your Honor, just so we're clear for the
5 record, I believe our objection here to this segment of
6 testimony, again, is not to basic background about the
7 agreement but where we have questions at 126:13 to 127:1 where
8 this, again, is a very similar objection and the way it's
9 being phrased is that this witness is stating what Teva is
10 warranting. But, again, we understand your ruling on the
11 prior objection.

12 SPECIAL MASTER VANASKIE: Same ruling. The objection
13 is overruled, and that testimony can be presented.

14 Now we go to page 136, line 9.

15 Go ahead, Steve.

16 MR. HARKINS: Sure. And I believe there are two
17 objections, 136:9 to 12 and then also to the answer at 136:15,
18 which can all be kind of taken together.

19 Your Honor, our objection here is different. It's a
20 relevance objection. This is a question about what Teva
21 informs consumers about the contents of the generic drugs
22 through the approved product labeling. There are no consumers
23 and -- warranties or representations that are made to
24 consumers through the product labeling are not at issue here.
25 We think it's, you know, unnecessarily confusing and not

1 directly relevant to any of the issues in the case.

2 SPECIAL MASTER VANASKIE: David?

3 MR. STANOCH: Thank you, Your Honor.

4 I won't reread them again, but there were topics that
5 Ms. Osmian was specifically designated on on oral and written
6 communications and statements to a number of downstream
7 entities, which include -- I am quoting now -- i.e.,
8 wholesalers, retailers, consumers, TPPs, end quote, you know,
9 regarding the product. And this is literally -- she was
10 designated about, statements made about the product
11 downstream. Labeling is a statement made downstream.
12 Consumers are the insureds of the TPPs, and they're basing
13 their reimbursement decisions on the statements that's in the
14 labeling. And I think this question still goes to the -- goes
15 directly to the heart of the matter.

16 It's certainly probative for the jury to understand
17 that the ingredients and the statements in the labeling are
18 what's being presented in the product that's being purchased
19 and at issue in this case. And she was the witness on this
20 topic.

21 SPECIAL MASTER VANASKIE: Go ahead, Steve.

22 MR. HARKINS: Your Honor, just to clarify, our
23 objection is not that this is not discoverable information and
24 that information about consumers is not a proper subject of
25 discovery or something that Ms. Osmian was prepared to testify

1 about. But for purposes of this trial, we don't think that
2 representations or pieces of the labeling that were provided
3 to consumers and the content thereof are relevant. It is
4 confusing. And even the way that it was just described by
5 counsel as somehow being relevant for the jury to know about
6 representations made to the ultimate beneficiaries who are not
7 part of the trial further downstream from the TPPs, none of
8 this is probative.

9 Again, the content of the labeling and what is
10 included generally is appropriate, but whether or not anything
11 was provided to consumers, the content of what was provided to
12 consumers or what they would have done with that information,
13 for purposes of this trial, is not relevant.

14 SPECIAL MASTER VANASKIE: How is this relevant,
15 David, for purposes of this trial?

16 MR. STANOCH: Because it's informing -- the purchase
17 wouldn't happen but for healthcare providers prescribing the
18 drugs and consumers going to the pharmacy counter to fill the
19 prescription, Your Honor. And TPPs would not have reimbursed
20 absent those two first steps.

21 And this is showing that for those things to happen
22 to trigger the TPPs' reliance on the purchase and payment,
23 right, to be in this situation to have to reimburse and pay
24 money for these products, that those contents are being
25 consumed -- are being conveyed by Teva. Right?

1 A TPP is not the one ingesting it. They're not the
2 one getting the prescription. This is just the basic facts of
3 the pharmaceutical industry.

4 MR. HARKINS: And, Your Honor, questions about what
5 the TPPs saw with the labeling or reviewed or relied on with
6 the labeling, it's just not what's being asked here. This is
7 about what reaches a consumer as far as the labeling. That's
8 not at issue in the trial. Those individuals are not here to
9 talk about it.

10 And, again, the specific line of questioning that
11 we've objected to, beginning at 136:9 to 12 and then 136:15 to
12 137:12 is not about anything that TPPs reviewed or what they
13 relied on. It's about consumers whose claims are not at issue
14 in the trial and are not going to be present at this trial.

15 MR. STANOCH: And we'll have other witnesses
16 testifying about what TPPs relied on, Judge, but this is
17 foundational to what that testimony and evidence is going to
18 be in terms of how prescription drugs actually work and in
19 terms of what is represented in the label. Right?

20 I mean, some of these questions, you know, any
21 information in the label concerning the contents and purity of
22 the drug will be reflected in the label, right? And she
23 answers that.

24 That's completely different. That's completely
25 divorced from anything about a consumer or a healthcare

1 provider or anything like that. But, again, this is
2 foundational testimony that the jury can and should hear about
3 the process of how prescription drugs and reimbursements
4 actually work.

5 MR. HARKINS: Your Honor, those just aren't the
6 questions that were asked.

7 SPECIAL MASTER VANASKIE: Yes, I understand that, but
8 I do think it is foundational. And so I will overrule the
9 objection and allow this testimony to come in. And that's
10 also to be consistent.

11 I know it's a little different, Steve, than the other
12 questions, but it's in the same ballpark.

13 MR. HARKINS: I think that finishes us for
14 Ms. Osmian, and I see Ms. Lockard has rejoined as well.

15 SPECIAL MASTER VANASKIE: Yes. All right. So we
16 have, as I understand it, two other Teva witnesses for today.

17 MR. STANOCH: Yes, sir.

18 MS. LOCKARD: It's Stefan Karlsson and Jens Nassall.

19 SPECIAL MASTER VANASKIE: Yes. I think we're going
20 to go to Jens Nassall next, if that's all right.

21 MR. STANOCH: Sure.

22 SPECIAL MASTER VANASKIE: Is that all right with you,
23 Victoria?

24 MS. LOCKARD: Sure. Let me pull them up here. Okay.
25 So the first line item was actually an opposition to

1 our counter. And the issue really for the counter, it just --
2 it simply provides his title. And the plaintiffs' designation
3 begins with, you know, this is -- you've been at Teva. It
4 just sort of goes into when he's been at Teva and what his
5 role is, but he never really introduces what Mr. Nassall's
6 title is at Teva. So that's simply all those lines represent.

7 SPECIAL MASTER VANASKIE: Where are we at?

8 MS. LOCKARD: So it would be at lines -- our proposed
9 counter would be page 32, lines 2 to 13.

10 SPECIAL MASTER VANASKIE: I have that. Okay.

11 Why is this objectionable, David?

12 MR. STANOCH: Sure, Judge. And I'm not going to
13 belabor some background, but there's really two issues here.

14 One is presentation-wise, this idea that we don't
15 show a clip of someone saying, hello, my name is Jens Nassall.
16 I'm currently the blah, blah, blah manager for Teva, I don't
17 think we need to do that. We can just do that by agreement
18 and putting that language in text on a -- on a video clip when
19 we're about to play it. Right? So I don't see that as an
20 issue, frankly.

21 And then this designation jumps sort of right in,
22 this counter. There's pages leading up to this, and they just
23 want to throw in, oh, since approximately March 2020, you have
24 another position about this.

25 I don't really see how that -- that's really helping

1 anything, especially given that we can just say, you know, on
2 the title when we play the video, current -- name, current
3 title.

4 SPECIAL MASTER VANASKIE: No, I think the question
5 and answer are fine. I'll overrule the objection.

6 MS. LOCKARD: So that takes us to page 97.

7 SPECIAL MASTER VANASKIE: All right. Let me get
8 there.

9 And this is your relevance objection?

10 MS. LOCKARD: Correct. This is a relevance objection
11 and a foundation.

12 So this is -- again, you know, previously, we had
13 talked about the 2011 audit of ZHP, which we talked about with
14 another witness. And I know you said you were going to look
15 again at that, and we actually sent Judge Bumb's discussion on
16 the record at the motion in limine hearing. I don't know if
17 you've had an opportunity to review that, but it really goes
18 into the details of, you know, what she ruled with respect to
19 other audits, other regulatory action, and this notion that
20 the plaintiffs have to connect the dots. It either has to be
21 connected to the valsartan at issue or it has to be probative
22 of a systemic problem that relates to the valsartan at issue.

23 And so, again, if it's just a -- you know, one
24 comment in an audit or one issue in an audit, then it doesn't
25 sufficiently connect the dots. And this line of discussion

1 here is discussing an email about a 2011 audit, and -- that
2 Mr. Pan Lin performed back in 2011, unrelated to the valsartan
3 at issue in this case, involving Teva's API.

4 So we renew that argument with respect to anything
5 that relates to this unrelated 2011 audit. And we think that
6 this discussion about emails about the audit likewise should
7 be excluded.

8 SPECIAL MASTER VANASKIE: All right. David?

9 MR. STANOCH: Your Honor, in the context of Mr. Pan
10 Lin's designations, Your Honor has already allowed the
11 testimony by Mr. Pan Lin about this audit he undertook. And
12 this is the exact same audit. And nothing that Ms. Lockard
13 has provided you since changes any of the same arguments that
14 I raised back then.

15 This audit was Teva auditing ZHP. It was auditing
16 ZHP, the specific Chuannan site at which the valsartan API at
17 issue in this case was made. It was regarding the quality
18 systems -- this is the audit scope, I am quoting. "Quality
19 system CGMP level," and it was specifically about the CGMP
20 issues regarding valsartan.

21 So we could not have more dots connected at this
22 point, Your Honor. We argued it before. I'm happy to talk
23 more about it.

24 But given Your Honor's prior ruling, I'll stand on my
25 prior arguments as to Mr. Pan Lin when you allowed testimony

1 about this audit.

2 SPECIAL MASTER VANASKIE: What about Judge Bumb's
3 ruling, doesn't that change the result here?

4 MR. STANOCH: No, Your Honor. No, Your Honor. We
5 addressed that -- we had that ruling in hand before, and we
6 argued it to Your Honor. And Ms. Lockard strenuously argued
7 it to Your Honor in the context of Mr. Pan Lin, because he was
8 the Teva auditor who went to ZHP multiple times over multiple
9 years.

10 Judge Bumb's ruling essentially -- which, again,
11 we've discussed and Your Honor has made rulings on as to
12 Mr. Pan Lin and these exact same audits, she basically said --
13 you can look at the verbiage. She basically said --

14 SPECIAL MASTER VANASKIE: I have looked at it.

15 MR. STANOCH: -- it would relate to valsartan or the
16 facilities at which it was made or systemic issues --
17 right? -- that would affect the various products at those
18 facilities.

19 This checks every single box, as Your Honor
20 recognized before. This is about ZHP. It's about the actual
21 ZHP facility, which is the exact same facility that makes the
22 same valsartan API at issue in this case. And it's regarding
23 a CGMP issue that Teva's auditors are identifying and
24 complaining about regarding ZHP's quality oversight and
25 manufacture of valsartan.

1 We're not trying to say, oh, there's a facility in
2 Greenland that makes generic aspirin and someone dropped some
3 rat poison into a vat of that aspirin, Teva is a bad actor.
4 It's nothing like that. This is tied by product, it's tied by
5 facility. And we've already -- and both sides' experts have
6 already been found reliable in part to testify about the
7 audits conducted by Teva, including this audit, which is an
8 ipso facto ruling that it's helpful to the jury.

9 MS. LOCKARD: Well, we disagree with some of the
10 representations made about that. It's not about Teva's
11 product at issue. Teva was not even getting API from ZHP at
12 this time period.

13 So it's not in the right time period, it's not the
14 right product at issue, and it's not systemic because it's
15 just a single observation. And so what the Court had said,
16 and the reason for Judge Bumb's ruling, is that we don't want
17 to have mini trials over all of these additional audits that
18 don't directly relate.

19 One of the issues in this 2011 audit -- and this goes
20 to the next -- this is relevant to the next objection we have
21 in the next line, but the discussion they're having is about a
22 PSD issue, which is a particle size distribution issue. It
23 has nothing -- that issue -- that violation has nothing to do
24 with valsartan whatsoever in this case. In this case there's
25 no -- there is no allegation anywhere that particle size

1 distribution is what contributed to the nitrosamine issue.

2 The essence of the judge's ruling is you can't --
3 just because you have some bad finding, you can't throw it all
4 in as a character assassination. It's going to extend the
5 trial. We're going to have mini trials on all of these
6 issues.

7 If Mr. Stanoch's rationale is applicable, then every
8 audit would come in because you can find some dot.

9 MR. STANOCH: That's not what we're asking for,
10 Counsel. We're not asking for every audit.

11 MS. LOCKARD: Well, so far you have.

12 SPECIAL MASTER VANASKIE: You're asking for this
13 audit, and I'm not sure how this audit is connected.

14 MR. STANOCH: Judge, again, we argued this already,
15 and you, Judge, allowed this in, and Ms. Lockard made the
16 exact same arguments before.

17 And this isn't just a particle size issue. If you
18 look at the actual document, the cover email and the audit,
19 right, it's Teva person -- audit personnel saying that there's
20 a serious failure at ZHP about not following their own change
21 control procedures as to valsartan. That's the exact same
22 quality failing when they switch the manufacturing process
23 from the TEA to the zinc chloride process. That's the same
24 issue, quality issue.

25 They also say in this that ZHP failed to investigate

1 out-of-specification results about the valsartan.

2 These are the exact same type of quality issues.

3 These aren't saying, oh, you know, there's pink specks on the
4 pill or that the bottle cap doesn't fit right. We're talking
5 about CGMP deficiencies that Teva found at ZHP in 2011
6 regarding specific regulations about change controls and
7 out-of-specification handling -- all right -- and that they
8 didn't handle it correctly as to valsartan.

9 MS. LOCKARD: I mean, we're happy to show you the
10 audits, Judge, so you can see that this is not related to the
11 same valsartan at issue in this case, it is not related to the
12 same issues found in this case, and it's before the time
13 period where ZHP was even supplying Teva.

14 MR. STANOCH: Your Honor, on that last point, that's
15 misleading, because at this time period Actavis was a separate
16 standalone company purchasing the same valsartan API from the
17 ZHP facility, right, and this is Teva looking at it separately
18 at the same time. Just because, quote, Teva wasn't purchasing
19 it at the time, well, a Teva subsidiary, right, that's in this
20 case, the Malta facility, was purchasing from this very ZHP
21 facility the very valsartan API that at this time Teva folks
22 looked at and said, oh, my gosh, they have serious risk
23 assessment investigation issues, failure to follow their own
24 change control procedures, and failed to conduct an adequate
25 investigation of valsartan out-of-specification results. At

1 the same time, Actavis is buying from this facility this exact
2 same product. That's highly probative.

3 And again, we've already allowed the testimony on
4 this from Mr. Lin, who is the auditor who actually went here.

5 MS. LOCKARD: Well, Your Honor, you said you would
6 talk a look at that issue as well after looking at the ruling
7 by Judge Bumb, so I don't think we can chew on that.

8 MR. STANOCH: Ms. Lockard, I hate to interrupt, but
9 your --

10 SPECIAL MASTER VANASKIE: David, you're interrupting.
11 Not your turn yet.

12 MR. STANOCH: I apologize.

13 MS. LOCKARD: I mean, the issue -- the fact that
14 we're having such discussion about this right now just shows
15 our point, that we're going to have to get into this, it's
16 going to turn into a mini trial. They have the 2012 audit
17 that post-dates this that addresses all the valsartan issues.

18 So far they've tried to bring out every Teva audit of
19 ZHP. And if we spend this amount of time on every audit that
20 has some theoretical, arguable dot connected to valsartan,
21 it's going to be contrary to the judge's intention in her
22 motion in limine ruling.

23 SPECIAL MASTER VANASKIE: I know you disagree, David.

24 MR. STANOCH: Yes. This is not every audit, Judge.
25 This is a five-page double-spaced audit. This isn't going to

1 be a mini trial. The objections here, by the way, are
2 relevance and foundation. Right?

3 And relevance is any tendency -- right? -- to be
4 probative of a fact or dispute in issue. It's regarding, the
5 case against Teva, its quality oversight of its supplier.
6 This relates to quality oversight of its supplier ZHP at the
7 facility at issue about the valsartan product at issue. So I
8 think we've certainly established relevance and foundation
9 that are being made here.

10 SPECIAL MASTER VANASKIE: All right. I'm going to
11 reserve ruling on this particular issue. I'm going to pull
12 the determination I made on Pan Lin's testimony and also look
13 again at Judge Bumb's ruling and make a final determination.
14 And I'll have that final determination for you by tomorrow.

15 But I do want to study it. It's obviously struck a
16 nerve on both parties, and I just want to look at it a little
17 more carefully.

18 MS. LOCKARD: Okay. Thank you, Judge.

19 I think that covers the next objection as well at
20 line 100.

21 SPECIAL MASTER VANASKIE: Page 100, line 16?

22 MS. LOCKARD: Excuse me. Yes, page 100, line 16.

23 SPECIAL MASTER VANASKIE: All right.

24 MS. LOCKARD: So then that takes us to page 101. I
25 think that -- actually, that's the same questioning on the

1 same email.

2 And page 101, line 14.

3 MR. STANOCH: I disagree, Ms. Lockard, on 101. This
4 is about Mr. Nassall, an email talking about the
5 qualifications of Mr. Pan to conduct audits, I think.

6 SPECIAL MASTER VANASKIE: Yeah. That's the exchange
7 at lines 9 through 16 on page 101.

8 MR. STANOCH: Yes, Judge.

9 MS. LOCKARD: Right. I mean, I can address this, but
10 it is part of the email where the discussion is about -- the
11 reason they're asking about Mr. Pan's qualifications is
12 they're asking about his qualifications with respect to the
13 2011 audit.

14 MR. STANOCH: Your Honor, you know Mr. Pan Lin --
15 again, this is a huge issue in the case about Teva's own CGMP
16 obligations is to audit every two or three years its
17 suppliers, including ZHP. And Mr. Pan Lin was there multiple
18 times at ZHP between 2011 and 2018, a month before the
19 recalls.

20 So the fact that there are Teva personnel from audit
21 and procurement talking about whether Pan Lin was qualified to
22 be doing those audits we think is highly probative of issues
23 that the jury should be able to hear.

24 MS. LOCKARD: So let me just respond to that.

25 So Mr. Wang -- so this is an email where Mr. Wang,

1 who is in procurement, and Mr. Nassall, who is in procurement.
2 They are not part of the audit team. They don't supervise the
3 audit team. They don't supervise Pan Lin. They're in the
4 procurement department. They negotiate the deal with the
5 supplier.

6 The audit department comes under the quality
7 department. They go in and they do the audits. They're
8 totally separate.

9 So Mr. Wang and Mr. Pan Lin -- excuse me, Mr. Wang,
10 Mr. Nassall are not part of the audit team.

11 So eventually --

12 MR. STANOCH: That's incorrect.

13 MS. LOCKARD: -- he's got two procurement people who
14 are talking about Mr. Pan Lin and his qualifications. And
15 there is a comment in the email by Mr. Wang where he makes a
16 statement about Mr. Pan's qualifications, and in somewhat
17 disparagingly.

18 But that's why counsel is asking Mr. Nassall, well,
19 did you ever share concerns about Mr. Pan's qualifications to
20 anyone at Teva.

21 Well, for one thing, this is misleading because
22 Nassall -- Mr. Nassall didn't have any concerns about Pan
23 Lin's qualifications, and he goes on to explain that in the
24 next designation.

25 But this question makes it seem as if -- he's

1 essentially misleading the jury to think Mr. Nassall had
2 concerns, and he doesn't.

3 And secondly, it's improper character evidence as to
4 Mr. Pan Lin. It's one person in procurement, Mr. Wang, who is
5 making some offhand comment about Mr. Pan Lin's
6 qualifications.

7 It's not appropriate character evidence. There's no
8 reputation or -- you know, issues that were noted at Teva.
9 There's no, you know, documents to indicate Mr. Lin was
10 somehow unqualified to do this. It's just simply Mr. Wang's
11 offhanded comment that he had some concerns about Mr. Lin
12 doing this, because, frankly, he was in China and this was an
13 inspection in a facility in a different country.

14 So it is misleading. It's impermissible character
15 evidence. I think it's prejudicial more than it is probative.

16 SPECIAL MASTER VANASKIE: I will reserve ruling on
17 this as well.

18 MR. STANOCH: Thank you, Judge.

19 And, Judge, at the end of this, if you want copies of
20 documents that are the subject of these designations, I can't
21 recall if we provided those. I think we did. But if Your
22 Honor needs --

23 SPECIAL MASTER VANASKIE: There are some, yes.

24 MR. STANOCH: Whatever you'd like, we're happy to
25 provide it to you.

1 MS. LOCKARD: And I'm in agreement, David, with that,
2 if we want to just give him the couple of documents that
3 relate to these counters.

4 SPECIAL MASTER VANASKIE: Why don't you confer and
5 agree on what those documents are and get them to me, please.

6 MS. LOCKARD: Sure.

7 SPECIAL MASTER VANASKIE: Are we up to page 110 now
8 or no? I guess not.

9 MS. LOCKARD: So if we go back to 104.

10 SPECIAL MASTER VANASKIE: Right.

11 MS. LOCKARD: I think we can address 104, line 19.
12 I am trying to get there.

13 So I think this is a different email. So I don't
14 have a -- you know, a strict objection -- I mean, other than
15 these discussions about what was happening in 2011, which, you
16 know, I do think this line, this row also applies to that in
17 your consideration of that.

18 But this goes a little further. Because even aside
19 from the ruling on whether the 2011 audit discussions come in,
20 at page 104, counsel pulls up an email. And these are some
21 preliminary questions, which is not really an issue. But the
22 meat of the questioning is then at page 106.

23 And in this email, they're discussing -- Mr. Nassall
24 had written this email where basically he was saying: After I
25 heard there were some QA issues with Huahai's valsartan in

1 Goa, and after I heard, we probably should avoid Huahai in the
2 future, and then he goes on to question about this.

3 And I do have a problem about generally with a
4 hearsay objection of this, because this is talking about
5 without attribution to what specifically he heard, who he
6 heard it from. We don't know if he heard it from somebody at
7 Teva, we don't know if he heard it from somebody at ZHP or a
8 third party, but he's just talking generally about something
9 that he had heard.

10 So I have a hearsay objection to this in addition to
11 all the additional objections related to the relevance
12 argument.

13 And he's even asked in this at line 7, page 107: And
14 do you recall who you heard that from?

15 And he says: I can't recall.

16 SPECIAL MASTER VANASKIE: David?

17 MR. STANOCH: Your Honor, it's difficult to respond
18 because I'm hearing lots of different vague -- I don't mean
19 this pejoratively -- bases for the objections. I hear
20 hearsay, I hear something prejudice. I'm having a hard time
21 responding.

22 But I'll start with relevance. That Mr. Nassall both
23 in a -- he wrote this email. So it's a business record. I'm
24 asking a 30(b)(6) witness, right, both in his individual and
25 corporate capacity, about a Teva business record, an email,

1 that he wrote in which he said, essentially, we've been
2 experiencing problems with Huahai's valsartan and there's
3 issues there and we should avoid them in the future.

4 I'm not sure how that's not relevant. Right? That
5 certainly goes to Teva's, if not Mr. Nassall's, state of mind
6 in terms of whether they found Huahai, ZHP, to be a reliable
7 or good API supplier, specifically as to valsartan, and that
8 it was experiencing issues.

9 But he goes on this email to say, well, Huahai is
10 still one of the biggest exporters of API to the US and we
11 can't avoid this opportunity to work with them. Right?

12 This all goes to Teva's and Mr. Nassall's state of
13 mind and motivations and knowledge about ZHP's approach to its
14 production and quality handling of valsartan.

15 And if I missed something that Ms. Lockard said,
16 Judge, I'm happy to address it, if you think I missed
17 something, but I'm trying to address the smorgasbord of things
18 I think I heard.

19 MS. LOCKARD: So we've been very selective and
20 surgical with the hearsay objections. You'll find very few of
21 those. And I -- you know, I agree, there are certain business
22 record exceptions that apply to emails and to business
23 records.

24 But this goes beyond that. This is essentially
25 hearsay within hearsay because he's talking about something

1 that he heard about Huahai.

2 If you read the transcript, this is not Mr. Nassall's
3 impression. In fact, his impression is the opposite. He's
4 saying to his colleagues, look, I have heard this stuff about
5 Huahai and its problems, but let me tell you, we've looked
6 into this before, and every time we've looked into it, it has
7 been an issue that wasn't with Huahai, it was with --
8 something that was going on at the Goa plant with respect to
9 differences in -- he goes on to this sort of differences in
10 their machinery or how they're calibrating.

11 But the point is, Mr. Nassall saying to his
12 colleague, look, I have heard these rumors that there are
13 concerns about Huahai, I'm telling you, those are false, you
14 know, concerns. We've looked at it. We feel like they are --
15 they are fine suppliers. And he does say, yeah, they're an
16 important supplier, but he's never -- Mr. Nassall is never
17 saying in this that he thinks there's a problem with Huahai.

18 And so to allow this hearsay to come in, where
19 somebody is saying that Huahai is a problem but we don't know
20 who said it, we don't know when or where, we have no basis for
21 that, it's compounded by the fact that it's prejudicial and
22 it's hearsay.

23 SPECIAL MASTER VANASKIE: It certainly seems to me to
24 be hearsay.

25 MR. STANOCH: Your Honor, the QA issues that he's

1 referring to in this email come right on the heels of the last
2 exhibit and audit report, right, about Huahai and ZHP, where
3 those folks were talking about the same QA issues that he's
4 talking about now.

5 And even -- and even if it is hearsay -- which now I
6 feel like we're arguing documents and not testimony, and I
7 think that's a different analysis. And Your Honor should
8 reserve if that's the way we're going because you should have
9 the document in front of you versus what either counsel say
10 testimony says about the documents.

11 I think that at least it's certainly a non-hearsay
12 purpose, at a minimum, in this admitted business record about
13 its notice and effect on the listener, Mr. Nassall.

14 MS. LOCKARD: Well, I don't know how we can argue
15 designations without getting into the documents because a lot
16 of the testimony is about the documents.

17 I mean, this one falls within the issue, the general
18 issue of us moving to exclude the 2011 discussions about the
19 audit.

20 I mean, if we want to pull this email and include it
21 with the couple of others we're sending, I'm fine with that.

22 But we do maintain our objection. I mean, we just
23 don't have -- we don't have enough information, you know, to
24 be able to say that this rumor about the quality issues is
25 something that's reliable or, you know, who said it. So I do

1 feel that it falls squarely within the hearsay objection.

2 MR. STANOCH: Again --

3 SPECIAL MASTER VANASKIE: As I listen to your
4 arguments and as I read through this testimony, it occurred to
5 me that this is really a fight over the admissibility of the
6 email or the document as opposed to somebody's interpretation
7 of it in a deposition.

8 MR. STANOCH: That may be right, Your Honor.

9 SPECIAL MASTER VANASKIE: Yeah. Illuminate me on
10 this point.

11 If this is a breach of warranty claim being
12 presented, why is all of this so hotly contested?

13 MR. STANOCH: If that's to me, Your Honor, I think
14 the answer is that this is not just a breach of warranty.
15 There's consumer protection law and fraud claims, which go --
16 which touch on the deception or unfairness and, frankly,
17 knowledge of issues that we're complaining about. Here, it's
18 knowledge of quality over -- CGMP deviations and quality
19 oversight lapses at ZHP on the part of Teva.

20 And of course, you know, punitive damages, Judge Bumb
21 hasn't bifurcated. I mean, this would all go to the state of
22 mind of Teva in that it's identifying early on issues at
23 Huahai about ZHP and keeps buying for another seven years
24 anyway.

25 MS. LOCKARD: I don't see how that's relevant to

1 fraud. I mean, the issue with respect to fraud, the claim
2 with respect to fraud and consumer protection is that somehow
3 we hid what was going on with the nitrosamine issue. And none
4 of this 2011 stuff or these extraneous audits relate to that.
5 It doesn't tend to suggest that Teva knew about the
6 nitrosamine problem or that it hid it in any way or that it
7 was deceptive with respect to that.

8 I mean, if anything, you know, plaintiffs' argument
9 is, well, we should have done better audits, but that has no
10 bearing on the fraud claim.

11 MR. STANOCH: I would just strongly disagree, Your
12 Honor. This is not just about NDMA qua NDMA. Among our
13 allegations and things which we will show to the jury at trial
14 is that these products were represented to have certain
15 characteristics and manufactured in a CGMP-compliant manner.
16 This is percipient evidence from percipient witnesses of Teva,
17 who is obligated to oversee CGMP issues at ZHP, saying that
18 there were CGMP deviations; meaning that the products were not
19 what they were supposed to be, products made in the
20 CGMP-compliant manner.

21 It's not just -- this is not a case about blinders of
22 did Teva know that nitrosamines were in there before 2019.
23 It's more than that. It always has been more than that.
24 There's been numerous orders by Judge Kugler for the last six
25 years to that effect.

1 MS. LOCKARD: The CGMP deviations have to have some
2 relevance to the nitrosamine issue. You have to be able to
3 connect whatever the CGMP violation was to the cause of the
4 nitrosamine issue. And that is where the disconnect is.

5 You know, plaintiffs -- you know, they want to throw
6 in any CGMP violation that came up in an audit to say, well,
7 you know, they were sloppy. And that's just not what Judge
8 Bumb held, and it is a problem, because it doesn't have
9 direct -- I mean, if there was a CGMP violation that was some
10 sort of a smoking gun, I mean, they would have something. But
11 they just want to throw up all -- every violation and
12 deviation they can find and say, you know, this was a bad
13 company, and that's inappropriate character assassination.

14 MR. STANOCH: I just disagree that that's what we're
15 doing, Judge. We argued this with Mr. Pan Lin.

16 MS. LOCKARD: Sorry. I keep hitting my video of
17 Mr. Nassall chiming in.

18 SPECIAL MASTER VANASKIE: Does this all relate to the
19 issues I've reserved on?

20 MS. LOCKARD: It does.

21 MR. STANOCH: I would say in part but not completely,
22 Your Honor. And that's why -- unfortunately, when you say it
23 may be about the document, that may be true, because part of
24 the document talks about "QA issues at Huahai's valsartan,"
25 and others separately talk about purchasing from Huahai and we

1 can't afford not to have them as our supplier, blah, blah,
2 blah. So I would say it doesn't completely overlap with what
3 we talked about before.

4 SPECIAL MASTER VANASKIE: What documents will you be
5 sending me?

6 MR. STANOCH: My suggestion, Your Honor, would be for
7 whatever excerpts you say you're reserving ruling on, we will
8 send you specifically those exhibits.

9 So, for example, if we're looking at 104:19 through
10 105:11, we will send you the email that is the subject of that
11 question. That would be my proposal.

12 I'm also happy to send you every exhibit for every
13 transcript, but --

14 SPECIAL MASTER VANASKIE: No.

15 MR. STANOCH: -- I'm happy to focus it.

16 SPECIAL MASTER VANASKIE: No. Stay focused.

17 MS. LOCKARD: I think we have enough to do.

18 I would propose we send the emails that are the
19 exhibits, but also the audit which --

20 MR. STANOCH: That's from what was reserved earlier.
21 Right. Yes. Whenever he says -- the Judge says this excerpt
22 I'm reserving, whatever was the subject of the testimony,
23 we'll send him.

24 SPECIAL MASTER VANASKIE: So I've reserved ruling so
25 far on objections that cover pages 97 through 107.

1 MR. STANOCH: I think so.

2 MS. LOCKARD: That's what I show.

3 MR. STANOCH: Yes. I agree.

4 And we will send you the two exhibits which I believe
5 are encompassed by those seven or so designations, if that's
6 okay, Judge.

7 SPECIAL MASTER VANASKIE: That would be fine.

8 MS. LOCKARD: So that takes us to page 131.

9 So this gets into a line of questioning where
10 Mr. Stanoch asked the witness -- this particular designation
11 here that we've objected to, it -- our objection is that,
12 number one, it's argumentative, it lacks foundation, and it
13 misstates his testimony.

14 We also think it's -- we have a relevance objection,
15 and we think it's prejudicial, confusing, and misleading.

16 So the issue is that he sort of jumps into this, oh,
17 so you never said that price is the only issue for valsartan
18 API.

19 And he says: I would not say that right now.

20 Have you ever said that?

21 Not that I can recall.

22 I think that alone lacks foundation, and it is also
23 misleading and is argumentative because it suggests to the
24 jury that he has said that.

25 This ties very closely into the next designation at

1 page 132 --

2 SPECIAL MASTER VANASKIE: Before you go to 132,
3 Victoria, you have a counter-designation at page 130, lines 15
4 to 24.

5 MS. LOCKARD: Right. And that was my -- so that's
6 somewhat contingent, that, you know, at a minimum, if this
7 testimony comes in, I think we should have the opportunity to
8 present our counter.

9 MR. STANOCH: Your Honor, I received the counter
10 before this even went in.

11 If -- we'll agree to the counter if they withdraw the
12 objection, because obviously the question we designated at
13 131:1 was the follow-up to the Q and A immediately before it.

14 SPECIAL MASTER VANASKIE: All right. So I will allow
15 the counter and the designation. So the jury will be
16 presented with evidence from line 15 through 24 on page 130
17 and lines 1 through 6 on page 131.

18 MR. STANOCH: Understood.

19 MS. LOCKARD: Understood. Okay.

20 SPECIAL MASTER VANASKIE: I think we go to page 132
21 now, lines 4 to 8 -- line 4 to page 133 line 8.

22 MS. LOCKARD: So we object to this designation based
23 on relevance, prejudice, it's confusing and misleading.

24 This is an email discussion that he's being
25 questioned about with respect to another supplier,

1 Dr. Reddy's. Dr. Reddy's was an API supplier. They were not
2 providing API supply in the US for valsartan, first of all.

3 And so there is an email -- the email discussion is
4 talking about some issues with Dr. Reddy and we cannot use
5 Dr. Reddy. Okay?

6 So they're talking about, well, then we need to
7 figure out who are replacement suppliers.

8 And Dr. Reddy is essentially emailing back and
9 saying, well, you know, we're not getting the business, why
10 aren't we getting the business.

11 And within that email -- and it's very -- it is
12 difficult to do this without having the email, you know,
13 because --

14 SPECIAL MASTER VANASKIE: Yeah, it is.

15 MS. LOCKARD: -- it makes it just -- I mean, it makes
16 it very misleading to be able to look at this just in a silo.

17 SPECIAL MASTER VANASKIE: Why is this being
18 designated, David?

19 MR. STANOCH: Your Honor, this is a procurement
20 executive at Teva telling his boss, Jens Nassall, the
21 deponent, who is also a 30(b)(6) on procurement issues,
22 that -- and I quote -- valsartan US, price is the only issue
23 as you said, end quote.

24 So this is -- this is Teva's procurement people,
25 right, saying that it's simply cost is the only factor, price

1 is the only issue when you're buying valsartan US grade.

2 And then it goes on, the email says: What about
3 Huahai? It certainly is probative of what -- of Teva -- and
4 we heard a lot of this from Torrent about cheaper Chinese API.
5 It's a similar type of issue, that they're trying to get the
6 jury can hear that the only issue to Teva, per their
7 procurement department, is price.

8 SPECIAL MASTER VANASKIE: Then we'll go to the
9 counter-designation, page 133 at lines 20 to 24.

10 And he says --

11 MS. LOCKARD: It goes on -- oh, I'm sorry.

12 SPECIAL MASTER VANASKIE: -- Right. So, I mean, you
13 can see my email below that I did not say anything like that,
14 that the price is the only issue.

15 MS. LOCKARD: Right. And that's because what he
16 actually said in the email when he's being asked, well, what
17 do we tell Dr. Reddy about why we're not going to use them?
18 And he said: There are much better options with lower prices.

19 That's what Nassall said, there are better options
20 with lower prices. He never said price is the only issue.

21 So Inbal Kan-Tor, who's responding -- and she's
22 basically saying, well, here's what I'll tell Dr. Reddy. She
23 says just: Valsartan US price is the only issue, as you said.

24 So she's representing what Nassall said. And the
25 counter goes on to explain that reason, I never said that.

1 Because not only did he not say it, it's also a misleading
2 suggestion that that's even what he meant. Because he
3 specifically said there are better options with lower prices.
4 So price isn't the only issue.

5 So it's confusing, it's misleading, and it's very
6 prejudicial. I mean, this isn't even in respect to ZHP or --
7 you know, this is about Dr. Reddy's, which is a product that
8 wasn't even used.

9 MR. STANOCH: Your Honor, again, it's a laundry list
10 of things I'm hearing there. There's nothing in this email
11 about the better product at all. This is classic impeachment
12 evidence. Right?

13 This is Mr. Nassall if he's in the chair. Right?

14 I can put an email in front of him, especially as a
15 30(b)(6), to say, here's your report to, saying you said, sir,
16 that for valsartan US grade, price is the only issue.

17 And then he can say, oh, well, I didn't say that.
18 And he can try to, you know -- but a jury can evaluate that.
19 Absolutely they can.

20 MS. LOCKARD: I mean, I'm trying to share my screen,
21 but this is -- can you see the document?

22 SPECIAL MASTER VANASKIE: Yes.

23 MS. LOCKARD: This may be helpful.

24 So this is from Mr. Nassall where he says: Clear
25 answer is that we have better options with much lower prices.

1 That's what he said. Better options, meaning -- you
2 know, presumably -- I don't know, you know, better quality,
3 better suppliers.

4 But he just said with much lower prices. He never
5 said price is the only issue.

6 What plaintiffs have latched onto is Inbal Kan-Tor's
7 response where she puts: Valsartan US, price is the only
8 issue, as you said.

9 And Mr. Nassall, in the counter that I provided, goes
10 on to say, That's not what I said. Read the email.

11 And so, you know, certainly we can make that argument
12 to the jury, but it's just a diversion. It's a waste of time.
13 It's confusing and prejudicial. And, I mean --

14 MR. STANOCH: Your Honor --

15 SPECIAL MASTER VANASKIE: We need to move on. We're
16 spending a lot of time on this.

17 MR. STANOCH: Yes.

18 SPECIAL MASTER VANASKIE: My ruling is they both come
19 in, both the designation and the counter.

20 MR. STANOCH: Understood. I don't want to spend any
21 more time, but, Judge, because we got the counter the other
22 night, I'd ask that on the next page after the counter, the
23 134:1 through 4 come in, my follow-up after what he said.

24 MS. LOCKARD: So you're talking about: Well, she
25 doesn't say what you wrote below. She's just saying as you've

1 said, right?

2 And he says: That's what she said there.

3 MR. STANOCH: Yes.

4 MS. LOCKARD: Okay. That's fine.

5 SPECIAL MASTER VANASKIE: All right. That's in.

6 MR. STANOCH: Thank you.

7 MS. LOCKARD: So we go to page 135.

8 SPECIAL MASTER VANASKIE: Yes.

9 MS. LOCKARD: Okay. So this is foundation,
10 relevance, 402 and 404, as well as prejudice.

11 So this is -- the issue with this is Mr. Nassall --
12 there's, again, an email talking about -- there's a reference
13 to sensitivities with respect to Huahai previously. And
14 Mr. Stanoch asked the witness what he meant by that.

15 And he goes on to talk about, well, there's issues
16 with doing business in China, cultural background. You know,
17 he says cultural background of Chinese manufacturers versus
18 what is ours. And that's what I believe I was referring to as
19 a delicate situation.

20 And I think this comes close to there is a motion in
21 limine on this about, you know, not sending the jury a message
22 that would be disparaging of the Chinese manufacturer,
23 suggesting that somehow because they're non-US, Chinese, that
24 they are -- you know, to disparage them.

25 So that's an issue with respect to references to

1 China.

2 SPECIAL MASTER VANASKIE: David?

3 MR. STANOCH: Your Honor, this is -- this is the same
4 email we were just talking about, just a different section of
5 it. Right? And a subordinate was referencing a delicate
6 situation with Huahai. And I'm asking Mr. Nassall, the one
7 who is on this email and in his 30(b)(6) capacity, what is the
8 delicate situation with Huahai. Totally fair question.

9 And then he explains what it is. He says that
10 there's cultural issues. That's his answer.

11 Otherwise, this email is going to go up and it's --
12 frankly, without it -- I'm surprised you would think that it's
13 going to leave a misimpression with the jury that there's some
14 other secret, nefarious, delicate situation.

15 I don't say a single thing in this questioning, nor
16 would I at trial, trying to disparage Chinese companies. This
17 is the witness giving his answer of what he meant about
18 something that's mentioned in an email with his subordinate.

19 So, again, I am hearing the MIL ruling for the first
20 time, because it was really -- the only objection I think I
21 can see here was relevance. And it's, again, someone
22 explaining, right, something that he's a percipient witness of
23 about the delicate situation with Huahai.

24 I'm not sure -- I'm not sure what prejudice there is
25 to Teva for its own witness to clarify what was meant by that.

1 SPECIAL MASTER VANASKIE: Victoria?

2 MS. LOCKARD: Well, we do have the objection based on
3 404, character evidence, and that's what the MIL, the motion
4 in limine was based on.

5 So my objection is to the whole line of questioning
6 where he's asking about the delicate situation and then the
7 only answer is to talk about, you know, the Chinese
8 businesses.

9 So I don't think it's relevant. I don't think this
10 is appropriate for the jury to get into. And it's, you know,
11 a side diversion.

12 SPECIAL MASTER VANASKIE: Yes, I agree. I'll sustain
13 the objection.

14 My initial inclination was to disallow this inquiry
15 as irrelevant. I understand that the comment is in the email,
16 but I don't want to get into a whole inquiry about what the
17 cultural differences are. And I think that for that reason,
18 doing the balancing under Rule 403, it should be excluded.

19 I think the next one is page 150?

20 MS. LOCKARD: Correct.

21 MR. STANOCH: Yes, sir.

22 MS. LOCKARD: So page 150, we object based on 408 and
23 offered a compromise and settlement. We also object based on
24 relevance and prejudice.

25 The discussion here is counsel is asking the witness

1 essentially, well, you know, you get a very competitive price
2 for ZHP to this day, meaning now.

3 The witness goes on to say, well, you know, that's
4 true.

5 And then Mr. Stanoch says: Isn't that part of the
6 agreement that Teva entered with ZHP, requiring it to offer
7 lower prices?

8 And he's right. This was a settlement agreement
9 between ZHP and Teva where they have not set -- reached
10 agreement on any liability damages related to the trial or
11 costs and expenses of defending against a trial. That's still
12 out there.

13 But with respect to the recall costs, Teva and ZHP
14 entered into an agreement where there were various business
15 negotiations and terms and prices were reduced, because
16 obviously Teva had to, you know, expend a lot of money to deal
17 with this recall situation. And so as a result, ZHP dropped
18 its prices. And that was part of the settlement agreement.
19 And so now, you know, at least at the time of this deposition,
20 Teva was paying less for ZHP's API.

21 The issues with this, one, obviously, it should be
22 excluded because it's part of a settlement agreement. And,
23 secondly, the prices that Teva is paying now for API has no
24 bearing or relevance to the case. If there's anything to be
25 said about pricing, it should be narrowed to whatever price

1 Teva was paying for the valsartan API that was at issue that
2 was recalled. What they were paying and the competitive
3 negotiations or agreements surrounding that arguably would be
4 relevant.

5 But negotiations post-recall, where they're dropping
6 their price based on a settlement agreement, that's entirely
7 not relevant and inappropriate under 408.

8 SPECIAL MASTER VANASKIE: Yeah. I'm going to cut it
9 off and say yes, I think this is barred under Rule 404 -- or
10 is it 408? In any event, I think it's not relevant and it
11 shouldn't come in.

12 MR. STANOCH: Understood.

13 MS. LOCKARD: So moving to 152, our objection is that
14 it's argumentative, we made a foundation argument that it's
15 misleading, and also under 602, the witness himself said he
16 didn't understand the question.

17 So the question was: In your view, it would hurt
18 Teva's bottom line if it stopped sourcing API from ZHP.

19 In this particular answer he says no, and then he
20 goes on to say: And I also didn't understand, sorry.

21 So counsel rephrases the question and asks it again.

22 So I think just based on procedure, the witness
23 didn't answer it, said he didn't understand it, it should be
24 stricken.

25 My additional objection is that this witness doesn't

1 know what Teva's bottom line is or how it would be impacted
2 based on one API supplier. I mean, Teva's bottom line as a
3 global company is, you know, beyond the scope of this
4 witness's 30(b)(6) topics or his personal knowledge.

5 SPECIAL MASTER VANASKIE: Anything else on this,
6 David?

7 MR. STANOCH: I'd just simply say, Judge, if he was
8 live there, I'd ask the first question. He answered no. And
9 then he pauses and says, I also didn't understand, sorry. And
10 then I rephrase and reask.

11 I think that would be perfectly allowable in a live
12 situation. The jury can certainly evaluate a witness who
13 first answers forthrightly "no," stops, and then hedges a
14 little bit. That's all part of the Q and A on the subject.

15 And in terms of the 602 issue, Judge, both
16 individually and 30(b)(6), he's the procurement guy for Teva
17 about purchasing API, including for valsartan.

18 MS. LOCKARD: So he -- counsel -- I mean, he's right.
19 He could ask the question again, and he did ask the question
20 again in the deposition.

21 I had an objection to it, I said it's vague. Witness
22 says: Yeah, sorry, I didn't understand it.

23 So then Mr. Stanoch, as he appropriately did, asked
24 another question, and that is the next designation. So --

25 SPECIAL MASTER VANASKIE: Yes, I'm going to sustain

1 the objection here and exclude the testimony from page 150,
2 line 5 through -- really extends into -- up to page 152 -- up
3 to page 153, line 1.

4 And then there's a counter-designation at 158, lines
5 8 to 11. And that should come out as well, I believe.

6 Looking at 158, lines 8 to 11, it makes no sense to me, so...

7 MR. STANOCH: We'll withdraw 153:8 through 11 then.

8 MS. LOCKARD: I think that takes us to 167, page.

9 SPECIAL MASTER VANASKIE: That's what I have.

10 MS. LOCKARD: So this just seems -- he jumps to: Did
11 you discuss valsartan with anyone at ZHP at the event prior to
12 the June 20th dinner?

13 And it just -- it seems out of place, like there's no
14 foundation for it. We don't know, what dinner are you talking
15 about. Like this just seems -- I almost wondered if this
16 was...

17 MR. STANOCH: It's ZHP. He's talking about he went
18 to dinner with ZHP, Ms. Lockard.

19 MS. LOCKARD: But those -- you didn't designate
20 anything about the dinner before this.

21 I mean, if it's important to you to say this dinner,
22 but it's just sort of out of nowhere, because the designations
23 prior to this did not include anything about a dinner.

24 SPECIAL MASTER VANASKIE: My inclination was to
25 sustain it, because I didn't see how it fit in.

1 MS. LOCKARD: I don't know why it's relevant.

2 SPECIAL MASTER VANASKIE: Maybe you can explain
3 how -- David, I'll give you a chance to explain how it is, but
4 I don't see it.

5 MR. STANOCH: Sure. I mean, he was -- step back,
6 Judge.

7 He was in China at the time, at a conference, right,
8 and then went to dinner with ZHP. And then ZHP on June the
9 20th or thereabouts, right, informed Teva about genotoxic
10 impurity. Right?

11 So if we did a cut and paste there that we didn't
12 mention that he was at a dinner with them in China, I
13 apologize and would add it. But he was a percipient witness
14 who essentially was in China, right, went to dinner with ZHP,
15 and then next day they get news about the genotoxic impurity.
16 Right?

17 So this is just percipient evidence of what was
18 happening and what --

19 SPECIAL MASTER VANASKIE: But it's not tied in
20 anywhere. You're filling in all the blanks with your
21 narrative there, but it's not filled in looking at the
22 deposition designations.

23 MS. LOCKARD: Right. And there is one designation
24 before this which was not objected to, but it doesn't talk
25 about the conference or the dinner. It just talks about this

1 is the first time you were aware of the nitrosamine issues.

2 And --

3 SPECIAL MASTER VANASKIE: What page are you reading
4 from?

5 MS. LOCKARD: The prior designation, it was at 159,
6 page 7 to 21. And again, it wasn't disputed, so it's not on
7 your chart.

8 SPECIAL MASTER VANASKIE: Right.

9 MS. LOCKARD: I mean, I will say later on in the
10 deposition there is testimony designated about being at a
11 conference, but there's not really anything to tie in this
12 dinner and it's just sort of out of -- it seems irrelevant. I
13 don't see what that has to do with any of the claims.

14 MR. STANOCH: Your Honor, if this was an
15 administrative error and in the rush to get all of these to
16 you, Your Honor, which we thought would be done last month, if
17 we made one mistake in this spreadsheet and cut something out,
18 I apologize.

19 The whole point of this is simply that there was a
20 percipient event of Teva personnel in China with ZHP personnel
21 at almost the exact same time of the news of the NDMA was
22 breaking, and it provides very probative information about who
23 met with whom when and what they did or did not discuss.

24 And if the night before there was a dinner and ZHP
25 didn't tell Teva, right, that's something the jury can

1 certainly consider as to either defendant.

2 And I apologize if we cut something out. I'm happy
3 to address it separately with counsel or right now if you want
4 to give me a moment. I apologize.

5 SPECIAL MASTER VANASKIE: Let's take ten minutes.
6 You can address it right now.

7 MR. STANOCH: I apologize.

8 SPECIAL MASTER VANASKIE: We can take a ten-minute
9 break.

10 (Recess at 2:16 p.m. until 2:26 p.m.)

11 SPECIAL MASTER VANASKIE: We're back on the record.

12 David, over the break, the ten-minute break, did you
13 have a chance to look at this testimony and the testimony in
14 this area?

15 MR. STANOCH: I did, Your Honor. And thank you for
16 that.

17 Ms. Lockard was correct that there is a designation
18 not before Your Honor because there was no objection, which is
19 at 159:7 through 21. And that simply orients the questioning
20 we're about to talk about. It's just an email from June 20,
21 2018 about the notification from ZHP. So that's already in at
22 159. So that's just a framing statement.

23 And I think we had an error in our chart. I think --
24 and I apologize and thank you for the time. I think we would
25 want to begin the designation we were looking at 162:4, which

1 picks up with "and you mentioned CPI China."

2 And then there's the discussion about that.

3 And then he explains that he was there in China on
4 June 20th for the conference, and he had dinner with ZHP. And
5 that leads through the testimony that we were just looking at.

6 So I think it should be -- and in thinking of
7 completeness -- 162:4 through 167:15. And then I know there's
8 a separate objection, I think, but I'd want to do the
9 continuing on to 168:24.

10 That's all this -- so I guess I'd say 162:4 through
11 168:24.

12 MS. LOCKARD: Okay. Let me take a look at this.

13 MR. STANOCH: Of course. I understand.

14 I apologize to do this on the fly, but I was trying
15 to capture all of the questioning and answers about this
16 subject to avoid any other disputes.

17 MS. LOCKARD: So I read from 164:2 --

18 MR. STANOCH: I'm sorry, 162:4.

19 MS. LOCKARD: Excuse me. Yes. 162:4 through the
20 designation we were dealing with before the break, 167:12.

21 I don't have an objection to that -- all of that, so
22 I don't think we need to fight about anything.

23 But I do think there's kind of some extraneous stuff.
24 So I would ask that you take a look at it, if you could trim
25 some of that down. I mean, it seems a little bit cumulative.

1 Like he tells you the story and then you repeat it back.

2 But I don't have a strong feeling. If that's what
3 you want to spend your time on, I don't have a legal objection
4 to -- an evidentiary objection to that testimony up to 167.

5 MR. STANOCH: I am fine to work with you separately
6 without bothering the special master on that, Ms. Lockard.

7 SPECIAL MASTER VANASKIE: Fine.

8 MS. LOCKARD: Okay. And so was there something
9 designated after -- and with that in mind then, I would
10 withdraw the objection to 167:12.

11 SPECIAL MASTER VANASKIE: All right. So that
12 objection is withdrawn. There will be at issue I guess a
13 continuing -- your designation, David, went to 168:24, I
14 thought.

15 MR. STANOCH: That's what I said, Your Honor. I was
16 just, for completeness, looking at the whole back-and-forth,
17 but I'll work with Ms. Lockard on that.

18 SPECIAL MASTER VANASKIE: Okay. You could end it at
19 167, line 15.

20 MR. STANOCH: Yes, sir.

21 SPECIAL MASTER VANASKIE: Okay. Are we now at 169,
22 line 15?

23 MR. STANOCH: I think so.

24 MS. LOCKARD: I think so.

25 Okay. So we have a hearsay objection to this part of

1 the testimony and this designation.

2 MR. STANOCH: We'll withdraw it.

3 SPECIAL MASTER VANASKIE: All right. It's withdrawn.

4 MS. LOCKARD: Okay. So 169:15 to 170:6 is withdrawn.

5 SPECIAL MASTER VANASKIE: Is withdrawn, yes.

6 MS. LOCKARD: Okay. Moving on.

7 Okay. That takes us to page 185, line 5 to 8.

8 So this, our objection is Rule 602, lacks personal
9 knowledge and outside the scope of the 30(b)(6) topics,
10 because he does not -- he's not, as I said, part of the audit
11 team and he doesn't know -- he's not going to know what audits
12 were conducted of ZHP. So I don't believe that he has the
13 personal knowledge to answer this question, so we object.

14 SPECIAL MASTER VANASKIE: David?

15 MR. STANOCH: This is simply a situation, Your Honor,
16 where the answer that they -- he doesn't know is the probative
17 point, that the procurement officer in charge of buying
18 valsartan API and 30(b)(6) procurement person doesn't know
19 what the audit team is doing of ZHP. They should be working
20 hand in hand. That's what we're trying to show here.

21 SPECIAL MASTER VANASKIE: All right. I will allow
22 it.

23 MS. LOCKARD: So that takes us to 193.

24 So we object to this designation based on relevance,
25 prejudice and calls for speculation.

1 So the issue with this is -- so this is a discussion
2 after -- hold on a second. Let me get my document.

3 This is a discussion after the recall. And what is
4 being discussed in the document is, okay, well, if we can't
5 use ZHP, we need to find a new API supplier. And they
6 reference what's known as a BI index, which lists current
7 prices at the time.

8 So at the time of this email, which was post-recall
9 in 2018, they're quoting what the current pricing is
10 post-recall in 2018.

11 And I find that to be prejudicial and not relevant
12 because it has no bearing on what the prices were or the
13 competitiveness of the prices for the drugs that are actually
14 at issue that were sold prior to recall and recalled. So just
15 finding prices, a document that lists prices of what's
16 available later in 2018 is not relevant, is misleading and is
17 prejudicial.

18 SPECIAL MASTER VANASKIE: All right. David?

19 MR. STANOCH: Your Honor, that timeline is incorrect.
20 Teva did not initiate its recalls till I believe July 27th of
21 2018. The emails are all dated June 28, 2018.

22 While they may have put a hold on product that they
23 were selling themselves, Teva product remained in the market
24 and was being sold at this time. And in fact, the email
25 string begins all the way down earlier in June as well.

1 So the fact -- even assuming that Ms. Lockard is
2 correct that post-recall pricing is not relevant, which I
3 disagree with, this is all happening in June, when -- before
4 Teva has announced its recalls. And it's showing that -- and
5 it's also showing almost contemporaneously, you know, before
6 the issues, that ZHP product was markedly cheaper than what
7 else was in the market pre-recalls.

8 MS. LOCKARD: So June 28th -- maybe I should restate.

9 The recall had not happened on June 28th, and counsel
10 is correct about that, so I stand corrected. But the issue
11 had been discovered, the hold had been put on.

12 The point is not when was it recalled, when did they
13 know. But the point is that this is just far later in time
14 than when the pricing negotiations took place for the API.

15 So it doesn't suggest what they want it to suggest,
16 which is they're trying to argue that Teva was using the
17 lowest cost API supplier. And that doesn't show this. It
18 shows that ZHP was the lowest cost provider on -- in June of
19 2018 when the events were coming to light. But what's
20 relevant is what was the competitive pricing at the time that
21 ZHP and Teva struck its deal.

22 So this -- this 2018 pricing, whether it's June 1st
23 or June 28th, it just doesn't have any bearing on what they
24 actually paid for the API at issue and whether it was in fact
25 then the cheapest supplier.

1 MR. STANOCH: And, Your Honor --

2 SPECIAL MASTER VANASKIE: I think it's relevant. You
3 know, you can disprove that point, but I think it's relevant
4 to prove the plaintiffs' point, and so I will allow it.

5 MS. LOCKARD: Okay.

6 SPECIAL MASTER VANASKIE: Are we at page 207 now?

7 MS. LOCKARD: Correct.

8 Okay. So 207, so the objection primarily is
9 cumulative. This question was asked again in the next
10 section, and it's a series of questions. It's repetitive.

11 And so if he -- if counsel wants to designate 209 --
12 I think 207 should come out, because it's entirely cumulative
13 and repetitive.

14 MR. STANOCH: Your Honor, I'll simply say I'm asking
15 this witness about an email, right, that he was writing about
16 the ZHP valsartan. And the questioning for this designation
17 and the next one go back and forth based on the witness's
18 answers. And it's not cumulative in that he's sort of
19 shuffling around about what he does or does not focus on the
20 email. So naturally I refocus him when we have to.

21 There's nothing -- and if you read it, I don't think
22 it's -- certainly not unreasonably cumulative. We're talking
23 about, you know, a few more lines. And I disagree that it's
24 cumulative.

25 SPECIAL MASTER VANASKIE: Yeah. I will allow it and

1 overrule the objection.

2 Now we go to page 209, line 4. And it goes down to
3 212, line 3.

4 MS. LOCKARD: So -- yeah. So we made another
5 cumulative objection here because they do ask the same --
6 almost the exact same question again. And what he's sort of
7 going over again and again is this question number 2 in the
8 email.

9 But I think, you know, if Your Honor thinks it's not
10 harmful to have him repeat that question, then the cumulative
11 objection I think is going to be overruled.

12 There is an objection, I'd ask that my objection on
13 the record be taken out of this designation, lines 20 to 21.

14 SPECIAL MASTER VANASKIE: Asked and answered, yeah.
15 That should be removed.

16 MR. STANOCH: Of course.

17 Counsel, can you tell me that line so I can write
18 that down?

19 MS. LOCKARD: It's line 20 to 21.

20 MR. STANOCH: Of page?

21 SPECIAL MASTER VANASKIE: On page 209.

22 MS. LOCKARD: Yeah, on page 209.

23 MR. STANOCH: Will do. Apologies, everyone.

24 MS. LOCKARD: I'm sure it was just an oversight.

25 Okay. So that brings us to 212.

1 So I had an objection as to cumulative on the chart,
2 but I'll withdraw that. I think that was my mix-up, that was
3 supposed to be on the prior line.

4 But my objection is as to page 215, lines 11 to 17.
5 And it's a Rule 602 objection, personal knowledge and
6 speculation.

7 SPECIAL MASTER VANASKIE: Yes. I'm inclined to
8 sustain that objection.

9 MR. STANOCH: This is, I'm sorry, 215:11 --

10 SPECIAL MASTER VANASKIE: 215, I think it would be
11 lines 10 through 17.

12 MR. STANOCH: I mean, the -- it's funny, Your Honor,
13 because this is the witness simply going on in his answer.
14 Right? I mean, there is no real question prior to that. It's
15 an "mm-hmm" which was picked up from me, and it's really his
16 answer to the prior question.

17 You know, we've heard any number of designation
18 battles where our side was being chastised for trying to cut
19 off an answer, and now Ms. Lockard is cutting off her own
20 witness's answer halfway through.

21 And it really gives the entire -- again, recall, Your
22 Honor, this also goes to demeanor and presentation. And the
23 jury can -- should be able to see the entire answer and
24 vacillation of this witness when he's answering the question
25 from the prior page.

1 MS. LOCKARD: So I don't agree that he's vacillating.
2 I think he's just rambling.

3 SPECIAL MASTER VANASKIE: He's rambling and he's
4 speculating. And that's the point.

5 MR. STANOCH: But that's his answer.

6 I mean, there's plenty of times I think they're
7 speculating other ways when they say things like, oh, nobody
8 in the industry knew, but that's the answer that's been
9 allowed most of the time in this process, Your Honor.

10 And here he is fidgeting through an answer and trying
11 to sugarcoat something that he just said. I think it's
12 appropriate. I mean, it's not -- it's not prejudicial. It's
13 his answer. It was unobjected to.

14 I'm not sure even what the objection is.

15 MS. LOCKARD: Well, there wasn't a question on the
16 record, and that's why I didn't object to it. But I don't
17 know that this is really part of his answer other than just
18 kind of thinking out loud about -- speculating on what ZHP was
19 thinking or why they would or would not do something. This is
20 not helpful to the jury, and it's confusing as well.

21 SPECIAL MASTER VANASKIE: Yeah. I don't see this as
22 helpful at all, so I'll sustain the objection.

23 Lines 10 through 17 on page 215 will be out.

24 I think we're up to page 238 now.

25 MR. STANOCH: Yes, sir.

1 MS. LOCKARD: Right.

2 SPECIAL MASTER VANASKIE: This is a
3 counter-designation, 238:4 to 13?

4 MS. LOCKARD: That is not, I don't believe. I
5 believe that's plaintiffs' designation.

6 So I don't have a strict objection to this
7 introduction of the email, these couple of questions about
8 this is an email to you and others and how it starts. So
9 maybe we don't even need to spend time on that.

10 But my objection really pertains to the subject of
11 the email and the testimony about that, which starts on
12 page 239, line 15.

13 SPECIAL MASTER VANASKIE: All right. So page 238,
14 lines 4 through 13 stay in.

15 MS. LOCKARD: Okay.

16 SPECIAL MASTER VANASKIE: Unless I sustain the
17 objection on page 239. So let's talk about that.

18 MS. LOCKARD: Yeah. Because it won't be needed if
19 you sustain the objection.

20 So this is discussion about an email where -- just to
21 lay the framework on the timeline, so initially ZHP had told
22 Teva that the issue with the nitrosamines was due to the
23 process change and that prior to the process change, that the
24 old ZHP API was not impacted by the nitrosamine issue.

25 All of the product in the US at issue in this lawsuit

1 for Teva was made under the new process.

2 But Teva globally was getting supply from ZHP in
3 other countries, in Belarus, in Liberia, Lithuania.

4 And so this email and part of the discussion, the
5 email is Teva realizes, well, now the old API is also
6 impacted, do we have product on the market involving the old
7 API. And the emails say, yes, we actually still have some
8 from Lithuania, Belarus and these other countries.

9 And there is an MIL on this with regard to non-US
10 Teva product. And the Court has ruled that Teva product
11 involving API and valsartan sold in other countries is not
12 admissible in this case.

13 So we think this falls within it, within that motion
14 in limine. We think it's irrelevant and it's prejudicial.
15 And that's our objection.

16 SPECIAL MASTER VANASKIE: All right. David?

17 MR. STANOCH: Your Honor, this is about what ZHP is
18 telling Teva. Right? It's saying that ZHP told Teva the
19 issue is only with the new process and then it turns out that
20 that's wrong. It's also the old process.

21 And Teva initially had its ANDA approved for the old
22 process API. We're not trying to -- we're not trying to argue
23 anything about what's going on in Belarus or Russia. If you
24 read it, read what this testimony is, it's what ZHP, a party
25 opponent, told Teva, another party opponent.

1 MS. LOCKARD: But it's misleading because it suggests
2 that we do have product in the US that was still on the market
3 that was impacted. And the email -- and the subsequent
4 discussion in the deposition makes clear that it's not.

5 So it's totally irrelevant. And it's a side track
6 from what was actually going on.

7 I don't have a problem with testimony or evidence
8 that ZHP had told Teva initially that the old process wasn't
9 involved, and I think there may be some designations on that.

10 I don't have a problem with what ZHP told, but I have
11 a problem with testimony that suggests that Teva still has
12 impacted product on the market in the US, because they didn't.
13 And that's going to lead the jury to think that we did. And
14 that's a very important factor when you're talking about
15 claims like fraud or consumer protection.

16 SPECIAL MASTER VANASKIE: All right. I'm going to
17 sustain the objection at page 239, line 13 and exclude that
18 which appears on lines 15 through 24 on page 239 and lines 1
19 through 5 on page 240.

20 MR. STANOCH: That's fine. I understand, Your Honor.

21 SPECIAL MASTER VANASKIE: And I believe that then
22 requires the elimination of the counter-designation at
23 page 238, lines 4 through 13. All right?

24 MR. STANOCH: Okay.

25 MS. LOCKARD: That takes us to 249, line 17. And I

1 have a relevance objection to everything after line --
2 page 252, line 6.

3 Wait. That doesn't match up, does it?

4 MR. STANOCH: No, it doesn't. No.

5 SPECIAL MASTER VANASKIE: No. It's 249, line 17, to
6 page 250, line 14, I think.

7 MS. LOCKARD: Sorry. I think that what I was trying
8 to say, not very well, is that I thought everything after
9 page 250, line 6 should be struck. And I made a relevance
10 objection, but it's just sort of like off the record, I need a
11 break.

12 SPECIAL MASTER VANASKIE: Yeah. That should be
13 stricken.

14 MS. LOCKARD: Hopefully that's not an issue.

15 MR. STANOCH: Okay. No, yeah. That's of course
16 fine.

17 So 250:7 through 10, yes, that's agreed, out.

18 MS. LOCKARD: Okay. So then we get to page 257,
19 line 19.

20 So we have a hearsay objection as to the Bloomberg
21 article and the references and quotations from the Bloomberg
22 article, as well as a relevance and prejudice objection.

23 Essentially what he's doing right here is Mr. Nassall
24 said that the way that he found out about the FDA inspection
25 and adverse findings at ZHP was that he saw sort of a

1 damning Bloomberg press article. And then counsel is asking
2 him about that. And there's quotations in the Bloomberg
3 article which may or may not be quoting from the FDA report.
4 It's hard to tell.

5 But I don't think that counsel should be -- or excuse
6 me -- that the witness should be testifying about what's in a
7 Bloomberg news article.

8 SPECIAL MASTER VANASKIE: David?

9 MR. STANOCH: Your Honor, this is classic
10 non-hearsay. We're not trying to prove the truth of the
11 matter asserted for the Bloomberg article to establish that a
12 FDA May 2017 inspection happened. The effect on the listener
13 is that Mr. Nassall had a present sense impression of reading
14 it, and then what was the effect on him? He turned around and
15 followed up with ZHP. That's all this is showing.

16 SPECIAL MASTER VANASKIE: Yeah. But it's showing
17 much more than that. I mean, my initial read of it was it was
18 classic hearsay. It's -- you're quoting the article.

19 MR. STANOCH: We're not seeking to admit the article,
20 Judge.

21 SPECIAL MASTER VANASKIE: And the finding that ZHP
22 ignored quality testing that showed unnamed drugs didn't meet
23 US standards according to an agency report posted online on
24 Thursday. And then it further says: The company didn't look
25 into the failures and instead passing results were recorded,

1 according to the report.

2 I find all of that highly prejudicial. It seems to
3 me to be classic hearsay. Maybe you're not admitting it to
4 prove the truth of the matter asserted.

5 For what purpose are you using it?

6 MR. STANOCH: It was showing the -- if Your Honor
7 wants us to take out the portions of the testimony where I
8 read part of the article to him, which would be 258:8 to 23, I
9 am happy to do that.

10 Before and after that, it's simply, again, the effect
11 on the listener, right, the reader, Mr. Nassall, he read
12 something. Whether or not it was true or not, it caused him
13 to react and reach out to ZHP.

14 And it's important to show that he didn't know about
15 this inspection. And it was a public news story -- whether
16 true or false, it spurred him to do this, it spurred him to do
17 that.

18 And I'm happy to take out, like I said, 258:8 through
19 23 where I quote in part the article.

20 SPECIAL MASTER VANASKIE: Victoria?

21 MS. LOCKARD: Well, my response is the question from
22 the get-go, it asks about -- this is you emailing ZHP a cutout
23 from a Bloomberg press release. So I don't know how we excise
24 that.

25 But the point of introducing this is not to show

1 present state of mind of Mr. Nassall. I mean, there's -- I
2 don't know what relevance that has, that he learned of this
3 FDA inspection. I mean, there's no question that Teva did
4 learn after the fact when it hit the press that there was an
5 FDA inspection. I mean, that's just not disputed.

6 So what's really going on here is they want to get
7 reference to that there was some bad news in the press about
8 ZHP, kind of blasting them on this issue.

9 SPECIAL MASTER VANASKIE: I'm going to sustain the
10 objection, and we'll exclude page 257, lines 19 through 258,
11 line 23.

12 And that takes us to 259, line 20.

13 MS. LOCKARD: So 259, line 20, our objection is a
14 602, personal knowledge, speculation objection. This is
15 really asking about the responsibilities of Teva quality,
16 which is outside of this witness's role in procurement.

17 And he doesn't know if Teva quality keeps track of
18 regulatory inspections. I mean, the fact of the matter is
19 Teva quality, they ask ZHP when they do audits for their
20 regulatory history. But this is suggesting that quality is
21 supposed to, you know, independently keep track somehow. I'm
22 not really sure what the point is.

23 But he doesn't know this. He doesn't know what Teva
24 quality does to, quote, keep track of the inspections. This
25 was asked of Mr. Vadsola and Pan Lin in the audit designations

1 about what they knew or didn't know. It was asked about Dan
2 Barreto, who we're bringing live. So I don't think this is
3 within his purview in procurement.

4 MR. STANOCH: Your Honor, may I?

5 SPECIAL MASTER VANASKIE: Yes. Absolutely, David.

6 MR. STANOCH: Your Honor, he answers the question.
7 He doesn't say I don't know. Right? He says, the quality
8 department should be the one, yes.

9 And the whole point of this questioning is Teva --
10 and other evidence will come in, but this is a piece of what
11 we need to show, Your Honor.

12 Teva didn't know and never asked ZHP prior to after
13 the recall about a 2017 FDA inspection. And quality -- and no
14 one in quality is going to be able to say they knew about it
15 or did anything about it. Right?

16 We saw this with Pan Lin, where, you know, he said he
17 didn't have the report. He didn't have it with him when he
18 did the audit a few months later.

19 And now this is establishing that the only way anyone
20 at Teva knew about it was this person, Mr. Nassall in
21 procurement, asked ZHP directly and said, could you give us an
22 unredacted copy, that the first time Teva said we want an
23 unredacted copy of a 2017 FDA inspection report is when he,
24 Mr. Nassall, in August 2018 asked for it.

25 And I think it's certainly probative and important

1 for us to be able to show that the quality people didn't have
2 it and didn't ask about it. The procurement people
3 acknowledge -- he says, unqualifiably, they should be the one,
4 yes. And then he says, well, I actually was the one who asked
5 for the unredacted report finally in August 2018.

6 MS. LOCKARD: That is -- that is an argument that
7 plaintiffs intend to make which we say is belied by the actual
8 evidence in the case to say quality didn't know about this,
9 didn't ask about it. That -- we'll address that later.

10 None of that goes to this designation. This
11 designation is asking about whether quality keeps track or
12 kept track or do you believe that they should keep track.

13 And then his response is, quality department should
14 be the one to do it.

15 I mean, he doesn't know. He's not in quality. He
16 doesn't know what quality does.

17 They made their point with Pan Lin about Pan Lin,
18 whether he knew about it or not. This doesn't even talk about
19 what quality didn't know about this or quality didn't ask for
20 it, or we're the only ones in procurement who did. That's an
21 argument.

22 But this question and answer is not appropriate. If
23 they want to challenge quality for not doing the right thing
24 or asking about it, then they need to ask quality, which they
25 did.

1 MR. STANOCH: Again, Ms. Lockard -- I'm sorry, Judge,
2 I don't want to go back and forth too much.

3 Ms. Lockard is having a counterfactual world of what
4 Mr. Nassall knew or didn't know. He answers the question, he
5 knows. He says quality is the one who is supposed to be doing
6 this. I'm doing this now, though.

7 How can this be outside of personal knowledge or,
8 frankly, the 30(b)(6) about Teva procurement, right? He's
9 saying quality should be asking about these things. He knows
10 that. He works with these people. It's part of the process
11 and procedures of what's going on, of who does what, and he's
12 doing something that some other person should have done a year
13 earlier. That's relevant.

14 MS. LOCKARD: Well, there's a pause, which leads me
15 to believe I have to spin up all of my time.

16 But I would just say that that's not what the witness
17 says. He's not saying that quality didn't do it and they
18 should have and that I was the first one to do it, so --

19 SPECIAL MASTER VANASKIE: Yeah. I will allow it just
20 for the content of the testimony.

21 I think each side reads something into the testimony
22 that may not be there. But I think it's relevant and will
23 allow it.

24 MS. LOCKARD: That brings us to 260 --

25 SPECIAL MASTER VANASKIE: I think that covers us

1 through 260:2 to 21.

2 MR. STANOCH: I would agree.

3 MS. LOCKARD: Yeah. I'm just looking through that.
4 I think you're correct.

5 SPECIAL MASTER VANASKIE: Okay. So I have us now at
6 266, line 20 through 267, line 4.

7 MS. LOCKARD: So we had an objection as to 602,
8 personal knowledge and what the audit team saw. I think to
9 move this along, if you're letting in the prior, I think your
10 rationale probably applies to this as well.

11 SPECIAL MASTER VANASKIE: It does. And so that's
12 overruled and that comes in.

13 Now I have us at page 312, lines 21 to 313, line 7.

14 MS. LOCKARD: Yes. So this is, again, the 408
15 argument, our 408 objection related to the offer of settlement
16 and resolution of the indemnity claims.

17 SPECIAL MASTER VANASKIE: Yeah. I think it's covered
18 by that, and I would sustain the objection.

19 MR. STANOCH: I was going to say, Judge, based on
20 your prior objection, certainly the -- I'll stand on my
21 position, but I understand for the last two designations, I
22 think the one designation at 312:21 through 7 is ever so
23 slightly different because it's simply that ZHP was giving a
24 refund to Teva for unused valsartan API. That goes to damages
25 and the value and worthlessness of the product, but I'm

1 understanding a sustain for the ensuing --

2 SPECIAL MASTER VANASKIE: As part of the settlement
3 agreement.

4 MS. LOCKARD: Yeah. I mean, his answer specifically
5 says I'd have to take a look at the settlement agreement. So
6 I don't think you can get the question in without the answer,
7 which --

8 MR. STANOCH: Well, he says yes, but -- right? He
9 says, if I recall correctly, then yes. This is what they
10 offered. And probably it would make any further questions
11 easier if we look at the settlement.

12 I mean, if you want to say stop at "yes."

13 MS. LOCKARD: Yeah. I mean, our objection would
14 stand, because I think that's the off -- I mean, it's the
15 offer to compromise, which is also excluded.

16 SPECIAL MASTER VANASKIE: Yeah, no. I'll sustain the
17 objection.

18 MS. LOCKARD: So that covers the 312:21 to 313:6 and
19 the 314:17.

20 MR. STANOCH: I have the same thing, Counsel.

21 SPECIAL MASTER VANASKIE: Yeah.

22 MS. LOCKARD: Okay. So that's it.

23 SPECIAL MASTER VANASKIE: So this concludes
24 Mr. Nassall?

25 MR. STANOCH: Yes, Judge.

1 SPECIAL MASTER VANASKIE: Let's see.

2 Go ahead, Victoria.

3 MS. LOCKARD: Oh. I was just going to say, you know,
4 the only caveat is that we're trying to -- we had sent
5 affirmatives on our witnesses to plaintiffs, and our
6 affirmatives really will be cut down based on what your
7 rulings are on these. So my next objective is to get through
8 finalizing those. And if we have disputes, we may have to
9 bring those up with the Court.

10 But given that we have the benefit of your rulings,
11 I'm hoping we can apply your logic and rationale and reach
12 agreement on most of those.

13 But that does conclude for today Nassall.

14 So we have Stefan Karlsson.

15 SPECIAL MASTER VANASKIE: Right. And I see, Daniel,
16 you're back now.

17 And we have just a few designations I believe,
18 Daniel, for Torrent witnesses.

19 MR. NIGH: That's right. I don't think we have more
20 than 10, 15 minutes.

21 SPECIAL MASTER VANASKIE: So we'll give Victoria and
22 David a 15-minute break here, and we'll take up -- are you
23 okay to continue, Ann Marie?

24 COURT REPORTER: Yes.

25 SPECIAL MASTER VANASKIE: We'll take up the Torrent

1 witness -- I'm going to get to it here in a second.

2 Paras Sheth, is that who it is? Or do I have the
3 names backwards?

4 MR. NIGH: That's correct, Your Honor.

5 SPECIAL MASTER VANASKIE: All right. And my notes
6 indicate that the first objection is at page 125.

7 MR. RAE: Yeah. That's what I have too.

8 SPECIAL MASTER VANASKIE: Yeah. And I have to say,
9 this was one of those witnesses who didn't know anything, it
10 appears.

11 MR. RAE: And, Your Honor, that's exactly right. And
12 that's -- well, with respect to this topic that he is being
13 asked about, that is exactly right. And that's really the
14 basis of our objection, that this is a witness, Paras Sheth,
15 who works in procurement for Torrent. He's responsible for
16 things like handling the relationship with the vendor,
17 handling the logistics, handling kind of pricing and
18 coordination of deliveries, stuff like that.

19 He's not the person who is responsible for the
20 quality department tasks that relate to supervising an API
21 vendor from a quality perspective, validating them, auditing
22 them, all of those things. There are people who are
23 responsible for that. We've seen testimony from these people.

24 Mr. Sheth is not one of those people. And so asking
25 him questions about his understanding of Torrent's

1 responsibilities with relation to things like validation of
2 vendors for API is more prejudicial than probative, because
3 his lack of knowledge doesn't prove anything. There are other
4 people -- that's not his responsibility. There are other
5 people at Torrent who are responsible for it who are witnesses
6 in this case.

7 SPECIAL MASTER VANASKIE: Daniel?

8 MR. NIGH: Your Honor, I actually think this one's
9 relevant. I think it's relevant for a number of reasons.
10 This is -- he is the general manager of procurement. So his
11 role is, when it comes to procurement, he is the person
12 responsible. And we lay it out at the end. It's laid out at
13 the end too. He talks about it at the very end of the
14 deposition as well.

15 He's responsible for obtaining the supplies that they
16 need in order to make their finished dose product. And so
17 that includes procuring the API from ZHP. Specifically he is
18 the contact person with ZHP, and he is the person who is also
19 handling negotiations with ZHP.

20 So when we talk about logistics, well, one of those
21 things is price. And there's going to be a lot of information
22 here in this trial that's going to be related to price. And
23 so to the extent that the defendants have put in pricing and
24 value and what sort of value there might be, that goes to this
25 issue.

1 And so the other part of it is there are certain
2 questions that are asked about validation and things of that
3 nature that nobody can speak to. I wish that we had some more
4 answers from somebody like Jaiswal, but he doesn't know some
5 of these issues either. So because of that, that's why we
6 have to have multiple parts of the chain, because they say the
7 quality people are supposed to be the people that know, but
8 there are some of these questions that Jaiswal didn't know
9 either. And so we have to show that Jaiswal doesn't know and
10 the person who is having the direct contact with the customer
11 or the direct contact with the API supplier also doesn't know.

12 MR. RAE: Your Honor, just two brief responses there.

13 I don't think it's accurate to say that Dr. Jaiswal
14 doesn't know about vendor validation processes or what was
15 done with respect to validation of ZHP as an API supplier. I
16 don't think that testimony exists, and I don't think --
17 frankly, I don't even think these questions were asked of
18 Dr. Jaiswal, who is the person they should have been asked of,
19 both in his 30(b)(6) capacity and in his personal capacity.

20 But separate from that, Mr. Nigh wove in discussions
21 of pricing issues into the conversation about our objections
22 to questions about validation.

23 I'm pretty sure we do not object to any questions
24 that may have been asked or any testimony that may have been
25 designating asking Mr. Sheth about pricing issues related to

1 procurement.

2 There's no disagreement here that that would be
3 within the scope of Mr. Sheth's responsibilities and that it
4 would be appropriate to ask him those questions. But that's
5 not the objection that we're talking about here. That's not
6 the questioning we're talking about here.

7 We're not making a blanket objection to Mr. Sheth's
8 relevance as a witness, although I think it's pretty limited.
9 We're making an objection to a handful of questions that have
10 been asked of him about areas of responsibility that are
11 outside the scope of his job responsibilities and outside the
12 scope of his personal knowledge, where plaintiffs want to
13 prejudicially play testimony to the jury showing that someone
14 at Torrent doesn't know about those things to create the
15 misimpression that these are things that no one at Torrent
16 knows about when that's simply not the case --

17 MR. NIGH: Your Honor, if I may, because there's a
18 big difference between what -- I'm not saying Jaiswal doesn't
19 understand a validation process. Okay. And he doesn't
20 understand USP Pharmacopeia guidelines.

21 But there are specifics within these questions that
22 Jaiswal doesn't know about a ZHP API supplier. There are
23 things that he doesn't know that are related to the 2017 audit
24 that happened of ZHP. There are things that he doesn't know
25 related to ZHP in the 2018 inspection that happened on

1 August 3rd where they could and should have known, but he
2 doesn't know. So we need to make sure that the person that
3 has contact with ZHP doesn't know these various issues as
4 well.

5 And that's why the questions are broad at first,
6 because the answer is broadly he doesn't have any idea. So
7 he's not going to know the specifics either. But that's why
8 it becomes relevant.

9 SPECIAL MASTER VANASKIE: Well, I think they're
10 relevant inquiries. The answers don't reveal anything, but
11 that's the point, I take it. So I will overrule the
12 objections and allow the testimony to be played for the jury.

13 And I think that covers everything for Mr. Sheth.

14 MR. RAE: Your Honor, if I can look through briefly.

15 I think we have some objections at page 145 and 146
16 that are not fully covered by that ruling you just made.

17 SPECIAL MASTER VANASKIE: Okay. Let's look at them.

18 There are objections from 143, line 24, to 146:6. So
19 there may be some particular questions that we need to drill
20 into.

21 MR. RAE: Your Honor, this question at 145:24 to
22 146:6 I think really drills into the impropriety and the
23 prejudicial nature of this line of questioning in general, but
24 it's also very clearly an improper opinion question being
25 asked of Mr. Sheth given the scope of his knowledge.

1 The question is whether or not he believes a certain
2 annual quality review provision of the quality agreement would
3 be beneficial to Torrent.

4 And, again, the quality oversight of ZHP is not part
5 of Mr. Sheth's job description. It's not part of his
6 responsibilities. He testifies clearly to that fact in his
7 deposition.

8 The quality department at Torrent oversees the
9 implementation of the quality agreement and the supervision of
10 an API vendor. And so Mr. Sheth properly answers that he has
11 no idea about this, but that testimony is both improper
12 opinion -- it's an improper opinion question of a witness who
13 has no specialization or expertise in answering this sort of
14 question to provide an opinion on this. And it's unduly
15 prejudicial, because, again, it's leaving the jury with the
16 impression that Torrent doesn't have any idea of these issues
17 when it's just that the person at Torrent who is not
18 responsible for this doesn't have any idea.

19 SPECIAL MASTER VANASKIE: Daniel?

20 MR. NIGH: Your Honor, this is still this same broad
21 objection. There's a lot of ways in which, you know,
22 something like this can be relevant. One is, you know, the
23 person who is having the direct contact, who is negotiating
24 the pricing, who is procuring the API, doesn't have any idea
25 about any of these issues? That in and of itself is a

1 problem, because, you know, to the extent that he's the front
2 person having these conversations with ZHP on negotiation of
3 pricing and various issues, you know, that's one issue.

4 The other thing is he's copied. He's cc'd on all
5 these emails. Like, we showed that earlier in the testimony.
6 So it's like you're being given this information, but you have
7 no idea what any of it means. What's the point of being cc'd
8 on all the emails?

9 So there's a lot of reasons as to why this could be,
10 you know -- and we didn't drill in to -- we didn't ask a ton
11 of questions to try to make this prejudicial because
12 we just -- in fact, there's questions above that that list all
13 the different things that would be in there. We left that
14 part out because broadly he doesn't know about it.

15 So we just cut to the chase, and that's what this is.
16 It's a cut to the chase and he just doesn't know.

17 MR. RAE: And, Your Honor, again --

18 SPECIAL MASTER VANASKIE: Go ahead.

19 MR. RAE: -- I think this is different because it's
20 asking an opinion question. But I think everything that
21 Mr. Nigh said is kind of highlighting why this entire line of
22 testimony and questioning is unduly prejudicial. And there
23 are other aspects of Mr. Sheth's deposition that were
24 designated that we're not objecting to.

25 There's lots of question and answer in this that

1 they've designated that we have no objection to because they
2 relate to topics that Mr. Sheth actually performed at his job,
3 but this kind of why would someone be copied on an email if
4 it's not relevant, I mean, that's the nature of email
5 communication in the modern business world. All the time
6 people are copied on emails that are tangentially related to
7 their job responsibilities, they don't actually relate to
8 things that they know. And there's no reason -- whether or
9 not these lines of questioning are relevant, there's no reason
10 to be proclaiming this to the jury except to create a
11 misimpression about the overall state of knowledge at Torrent.

12 And if plaintiffs want to probe into whether or not
13 the people who were responsible for validating API suppliers,
14 the people who were responsible for reviewing quality
15 agreements and implementing them and knew or were doing their
16 jobs, that's part of what this case is about. But asking
17 these questions about a -- from a procurement person whose job
18 was not to do this is not appropriate. And it's simply
19 designed to confuse and mislead the jury by making the jury
20 think that someone who doesn't know anything about this issue
21 answering they don't know is somehow information that should
22 be weighing into the jury's consideration of the ultimate
23 questions in this case. It's not.

24 MR. NIGH: Your Honor, it's highly, highly probative
25 because just the fact of the matter itself that the person who

1 is the front man, the only thing that he can talk to with this
2 API supplier -- this is the general manager of procurement.
3 This is the person who's been at the company for a long, long
4 time, that that person can only speak in business terms and
5 cannot speak in safety issues at all.

6 And so that already becomes a problem, because the
7 only person that can speak to safety issues, he has to go back
8 to somebody like Jaiswal to get the information and pass it on
9 to the API supplier. That in and of itself is relevant.

10 MR. RAE: Your Honor, frankly, it's not, but it's
11 actually -- to the extent it is relevant, it's probative of
12 the reasons why plaintiffs' argument ultimately shouldn't
13 succeed in this case, which is maintaining those sorts of
14 clean lines between business decision-making and
15 businesspeople and quality review and quality decisions is a
16 core function of the pharmaceutical industry. You don't want
17 your businesspeople considering quality issues, and you don't
18 want your quality people considering business issues. You
19 want to maintain separation, because quality decisions should
20 not be made in light of business concerns.

21 SPECIAL MASTER VANASKIE: All right. I've heard
22 enough. I've heard enough. I've heard enough.

23 I'm going to sustain the objection to the question at
24 page 145, line 24 through 146, line 6 because it's asking this
25 witness for an opinion, you know, why do you believe that this

1 information would be beneficial.

2 I'm objecting -- I'm finding fault with the question
3 itself but not with the lines of inquiry otherwise covered
4 during our discussion today.

5 So that will come out, but everything else stays in.
6 All right?

7 And that concludes Mr. Sheth, I believe.]

8 MR. RAE: Yes. Just to be clear for Your Honor, Your
9 Honor is saying that the same decision as to the general
10 propriety of this line of questioning is going to hold for the
11 testimony from 154:11 to 156:11?

12 SPECIAL MASTER VANASKIE: Let me take a look at that,
13 because I didn't have that down.

14 154 -- so 154, line 13 are you saying?

15 MR. RAE: There's a question at 154:17 to 154:22, and
16 then there's two questions that run from page 155:19 to
17 156:11.

18 MR. NIGH: These seem to be -- they're not asking an
19 opinion.

20 SPECIAL MASTER VANASKIE: These are not opinion
21 questions.

22 So the question -- I'm sorry, I missed these.

23 The question at 154, line 17, have you seen other
24 documents like this related to quality or risk for the
25 manufacturer of drugs?

1 And the answer was no.

2 There's an objection.

3 And what's the basis for the objection?

4 MR. RAE: Your Honor, I think the question here is
5 vague, but I'd be willing to withdraw our objection to this
6 question.

7 SPECIAL MASTER VANASKIE: All right. That's
8 withdrawn.

9 What's your next objection?

10 MR. RAE: At 155:19 to -- there's two questions and
11 answers here, but through 156:11.

12 SPECIAL MASTER VANASKIE: This was, did you have a
13 particular strategy that you utilized?

14 MR. RAE: Yes. And, Your Honor, I think the issue
15 here is, in part, a vagueness issue with respect to the way
16 the question is framed, which is why there's a form objection,
17 which is "particular strategy" is an incredibly vague
18 question, and I think it's why the witness struggles to answer
19 the question.

20 And in fact -- and this is an affirmative designation
21 which we're not getting into right now.

22 But the question and answer that immediately follows
23 this line of questioning on page 156, there's a question that
24 is a little bit more grounded and is not vague. And the
25 witness does provide an answer about the approach to

1 procurement of API that's used, which is that in the witness's
2 words, if the product is made for the United States, we have
3 to buy the API from valid DMF holders. So basically it's US
4 DMF holders and site has to be approved by the US FDA. That's
5 kind of the process and the predicate. That's the real answer
6 to these questions.

7 The vague questions that precede it that we're
8 objecting to, we're objecting to because they're eliciting no
9 answers I think because the questions are vague and confusing
10 and the witness doesn't really understand what he's being
11 asked to provide testimony on.

12 MR. NIGH: Your Honor, his answers aren't vague.
13 They're definitive. Do you have a strategy? No. I mean,
14 that's not vague. If he said, I don't know, I'm not sure what
15 you mean by that, you know, maybe we did, maybe we didn't,
16 those would be vague answers. His answer is definitive: No.

17 MR. RAE: Your Honor, that's why the focus needs to
18 be on the vagueness of the question. Because witnesses all
19 the time give answers that, like, aren't perfectly framed from
20 the perspective of saying I don't understand the question or
21 the question is unclear, can you clarify it. A perfect
22 witness would do that. But sometimes witnesses answer kind of
23 "I don't know" or "no" when they get a vague or confusing
24 question.

25 SPECIAL MASTER VANASKIE: I will sustain the

1 objection to the question on page 155, starting at line 19.

2 And that carries over to 156, line 3.

3 MR. NIGH: And then the second question is in?

4 SPECIAL MASTER VANASKIE: I'll sustain the objection
5 to the second question as well on page 156.

6 MR. NIGH: Your Honor, it's the last one -- I'm
7 sorry, I didn't mean to interrupt you.

8 SPECIAL MASTER VANASKIE: Go ahead.

9 MR. NIGH: The first one I thought maybe there's, in
10 the form itself, a particular strategy, but that's why the
11 second question is a better question than the first one. It's
12 objected to form, that's why it's reasked, and says, is there
13 any general strategy, any strategy? And he says: No.

14 So that covers the broad array of strategies. There
15 are absolutely strategies for purchasing things. He could
16 have said, we do this, we do that, we look for this, we want
17 to make sure that we're purchasing product that's the highest
18 quality, you know. A lot of different -- strategy is a
19 keyword in marketing function. And he comes back and he says
20 no.

21 So generally they have no strategy. I think that's
22 relevant, and it's probative.

23 SPECIAL MASTER VANASKIE: How is it relevant?

24 MR. NIGH: It's relevant in terms of the API that
25 they're purchasing, you know, that -- that ultimately in this

1 case, that's what's contaminated.

2 So if you have a strategy as to how you're going to
3 go out in terms of your purchase and procurement of API. So,
4 for example, we want to purchase the quality -- we want to
5 purchase API that's -- or use the ingredients that are of the
6 utmost quality, and that's your strategy. Okay? Well, then,
7 if that's the case, you're going to have a lower likelihood of
8 having problems like we had here.

9 Do they have a strategy to do anything of that
10 nature? No.

11 MR. RAE: Your Honor, I think that explanation is
12 precisely why we also have a 403 objection here, because as
13 you can see in the next question and answer that I referred to
14 earlier, there is an approach.

15 It does have concern -- like, it is necessary and
16 Torrent is aware of its obligations and Torrent is fulfilling
17 its obligations to make sure that its API suppliers have gone
18 through the proper FDA process, have a DMF that the FDA has
19 accepted, have been inspected by the FDA, and then they have
20 subsequent processes after they identify someone to verify
21 that they meet Torrent's quality standards.

22 SPECIAL MASTER VANASKIE: I'm going to sustain the
23 objection to the question as unduly vague.

24 I think you do cover the matter in your next question
25 starting on page 156, line 13.

1 I take it's that's been designated.

2 MR. NIGH: It has not.

3 SPECIAL MASTER VANASKIE: It has not been?

4 MR. NIGH: No.

5 MR. RAE: It's been designated by Torrent
6 affirmatively. It has not been designated by plaintiffs.

7 SPECIAL MASTER VANASKIE: Are there any other issues
8 with respect to Mr. Sheth's testimony?

9 MR. NIGH: No, that's all. But just to be clear, the
10 designation affirmative means that that would be something
11 that the defendants would --

12 SPECIAL MASTER VANASKIE: I understand. I understand
13 what it means. I understand what it means.

14 MR. RAE: For the record, if plaintiffs want to
15 designate that question, Torrent would have no objection to
16 designating that question and answer as a replacement for the
17 ones where Your Honor has sustained our objection.

18 SPECIAL MASTER VANASKIE: Yes. And let me make it
19 clear that I have sustained the objection to the form. I do
20 think it is unduly vague. Had you followed up with a question
21 like that which appears on page 156, line 13, that would have
22 been fine.

23 But that concludes Mr. Sheth's deposition.

24 MR. NIGH: Thank you, Your Honor.

25 SPECIAL MASTER VANASKIE: Let's give Ann Marie a

1 break. We'll resume at 3:45.

2 (Recess at 3:28 p.m. until 3:45 p.m.)

3 SPECIAL MASTER VANASKIE: Mr. Karlsson we're talking
4 about now, right?

5 MS. LOCKARD: Karlsson.

6 SPECIAL MASTER VANASKIE: Let me get up his testimony
7 and designations.

8 Okay. I think we're ready to go.

9 MS. LOCKARD: Okay. So first --

10 SPECIAL MASTER VANASKIE: Hold on. We're back on the
11 record, and we're going to be addressing the designations for
12 Stefan Karlsson.

13 And Victoria, go ahead.

14 MS. LOCKARD: Okay. I'm trying to get us through it.
15 Thank you, Judge.

16 So the first one is page 84, line 9. And so our
17 objection is foundation, relevance and 403, because it's
18 misleading and confusing.

19 Just to lay the groundwork for this, so this is a
20 witness who was in procurement, like our last witness, but the
21 difference is this particular witness works in the research
22 and development procurement for the European side of things.
23 So he was not directly involved in procurement with ZHP for
24 procuring the API at issue in the US, which is at issue in
25 this case.

1 He did have interactions with ZHP based on
2 discussions related to procurement for products that were in
3 development, not marketed, in the European sector.

4 So the way this starts off, we believe it's
5 confusing, because it just launches into when did you first
6 interact with ZHP, and it leads the jury to believe that this
7 is in relation to the API at issue in this case when it isn't.

8 So we propose --

9 SPECIAL MASTER VANASKIE: You have
10 counter-designations?

11 MS. LOCKARD: Yes, yes. We had proposed some
12 counter-designations to kind of line that up so it makes clear
13 what his role was and why he was communicating with ZHP.

14 SPECIAL MASTER VANASKIE: What is improper about the
15 counter-designations, David?

16 MR. STANOCH: First of all, Your Honor, none of the
17 four or so pages they want to counter-designate has anything
18 to do with the question. The question is, when did you first
19 start interacting with ZHP as a potential API supplier?
20 That's it. Did he know ZHP from a certain time.

21 There's other issues where it comes up later and they
22 want to inject that he only did certain things for certain
23 departments with Europe, which we will disagree with, and
24 we'll get to that. But adding in all these other things gives
25 the counter-misimpression, right, that he has no idea about

1 anything going on with ZHP when we're talking about the same
2 API that was going to the Europe and from the Teva Malta
3 facility to the US. I don't want to argue that now. But we
4 don't think it's necessary to have page upon page about him
5 talking about R&D or Iceland when the question simply is, when
6 did you know ZHP.

7 And, frankly, if that's the issue, I'll just take
8 out -- I'll just withdraw it.

9 SPECIAL MASTER VANASKIE: All right. You'll withdraw
10 84:9 to 84:19?

11 MR. STANOCH: Yes.

12 SPECIAL MASTER VANASKIE: And then we can withdraw
13 your counter-designation, I take it, Victoria; is that
14 correct?

15 MS. LOCKARD: Yes, that's correct.

16 SPECIAL MASTER VANASKIE: All right. So they're out.
17 Let's go to page 125, line 17 to 126, line 21.

18 And you have an objection based on speculation,
19 foundation?

20 MS. LOCKARD: Yes. So this --

21 SPECIAL MASTER VANASKIE: Go ahead.

22 MS. LOCKARD: This one cuts off before the end of the
23 question and doesn't include the following answer.

24 MR. STANOCH: I think it does, Counsel. The
25 spreadsheet says 125:17, which is a question beginning: Okay.

1 Let's talk a little bit about.

2 And then it goes through 126:21, which is the end of
3 the answer on the following page.

4 SPECIAL MASTER VANASKIE: Yes.

5 MS. LOCKARD: See, I think that this was a holdover
6 objection from the prior spreadsheet before it was updated.
7 Let me look real quick, make sure.

8 MR. STANOCH: Sure.

9 MS. LOCKARD: Yes. Okay. So we can withdraw that
10 objection.

11 SPECIAL MASTER VANASKIE: Okay. So that's in.

12 MS. LOCKARD: Okay. So the next page, 128.

13 So this objection, this gets into a line of questions
14 about the timing of when he discovered or heard about the
15 issue with nitrosamines. And we have a counter here to make
16 clear the first notice that was provided about the issue did
17 not mention nitrosamines. It said an unknown genotoxic
18 impurity.

19 And so our counter at 134 just clarifies that the
20 first notice did not include the identification of the
21 chemical compound or nitrosamine.

22 SPECIAL MASTER VANASKIE: David?

23 MR. STANOCH: I don't think the counter is really
24 necessary. The designation simply is orienting the witness,
25 right, to the email, which is the 22nd. Right? Which

1 actually is the date of the second notice, I believe, that was
2 sent. Right?

3 And he says, yeah, it's around that time about the
4 nitrosamine contamination.

5 And then pages later, the counter is talking -- he
6 says, the first time it might have been just -- the initial
7 notification was genotoxic impurity. That's not the question.
8 I'm asking about a document from June 22nd that talks about
9 the second notification when it said nitrosamine.

10 So I'm not sure how it's clarifying to add something
11 about a different notice that wasn't part of the question.

12 MS. LOCKARD: But it's misleading, and it's factually
13 inaccurate. The first notice was on the 20th, and it did not
14 mention nitrosamines. The second notice on the 22nd did
15 disclose nitrosamines.

16 MR. STANOCH: Right. And the question is: The first
17 time you heard about nitrosamine contamination, right?

18 MS. LOCKARD: Was on -- sorry.

19 MR. STANOCH: No, go ahead.

20 Judge, I don't want to fight about counters. If you
21 want to add the counter, I'll not fight the counter.

22 MS. LOCKARD: Yeah, I mean, because it says June
23 20th, so it's accurate just to include.

24 MR. STANOCH: I'm happy to move it along.

25 SPECIAL MASTER VANASKIE: You're putting in your

1 counter to the counter?

2 MS. LOCKARD: No. Our counter to his.

3 SPECIAL MASTER VANASKIE: The response would be 135:8
4 to 13.

5 MS. LOCKARD: I don't -- no. I think he's just
6 saying that he will agree to our counter of 134:23 to 135:7;
7 is that correct?

8 MR. STANOCH: That's right. But what the judge is
9 referring to is the spreadsheet said that we would have a
10 contingent counter then of 135:8 through 13. I think that's
11 what the judge is looking at.

12 SPECIAL MASTER VANASKIE: That's what I'm trying to
13 get to.

14 MS. LOCKARD: I see, okay.

15 MR. STANOCH: And in fact, maybe it should in
16 fairness go through 135:18, just to round it out.

17 MS. LOCKARD: So it would be 135:8 --

18 SPECIAL MASTER VANASKIE: 8 to 18.

19 MR. STANOCH: 8 to 18. That's probably fairer,
20 honestly. Just because he kind of says I'm not sure, and then
21 I clarify, and he says yeah later, yeah. So that way it's
22 clear.

23 MS. LOCKARD: Okay.

24 SPECIAL MASTER VANASKIE: So that will come in
25 through 135, line 18.

1 MR. STANOCH: Yes, Judge.

2 SPECIAL MASTER VANASKIE: Now we're at page 139.

3 MS. LOCKARD: So 139:8 -- so this is a discussion
4 that I think bears on the general causation issue before Judge
5 Bumb.

6 But essentially the next few designations relate to
7 Mr. Stanoch asking the witness about his knowledge of, you
8 know, the toxicology, the carcinogenicity of NDMA.

9 And Mr. Karlsson's only knowledge, remembering he's
10 in procurement, he's not on the toxicology side. But his only
11 knowledge is that he looked all of this up on a Wikipedia
12 page. And so these questions, I think, you know, it's going
13 to be governed by what Judge Bumb says.

14 But as a general objection, I don't think this is
15 within his personal knowledge. He's not a toxicologist, he
16 wasn't a 30(b)(6) witness, and he wasn't disclosed on these
17 issues. So his understanding about the toxicology of NDMA
18 that he got off of Wikipedia I don't think should be the
19 subject of jury evidence.

20 MR. STANOCH: May I?

21 SPECIAL MASTER VANASKIE: You may.

22 MR. STANOCH: Thank you, Judge.

23 Putting aside whatever Judge Bumb does next week for
24 sure, I think it's perfectly permissible for me to ask a
25 witness who said in a business record email, I looked up NDMA,

1 here's the link to the page I read. And then I say, did you
2 gather from the link X. And he says, I can't remember. And
3 then I follow up and I say, well, do you remember if NDMA can
4 do Y. He goes, oh, I'm not a toxicologist, I don't remember.

5 Again, my questions aren't about expert testimony.
6 I'm saying what did you learn or remember doing, because you
7 said, I looked at this and shared it with my colleagues. And
8 I'm saying, okay. So what did you -- what did you learn when
9 you looked at it. That's it. He says, I don't remember, I
10 don't remember, I don't know, I don't remember.

11 Which those are his answers, Judge. But we're
12 allowed to play that to a jury, that -- nothing against
13 Mr. Karlsson, maybe he was worried, maybe he was coached and
14 prepared very well. He was very, very, very nervous the
15 entire time of the questioning, procurement guy maybe, when
16 I'm asking about these contemporaneous emails that he wrote.
17 And I'm simply asking him, what do you personally remember.
18 He goes, oh, I'm not sure, I don't remember, I don't remember.

19 SPECIAL MASTER VANASKIE: He didn't remember
20 anything.

21 MR. STANOCH: That's right. And I think it's
22 certainly allowable for the jury to hear that someone who is
23 on the ground level of this issue -- and this will come out
24 later. Even though he's procurement, he was being asked by
25 bosses to look into this issue. And he himself took it upon

1 himself and figured things out on the internet in five minutes
2 that Teva quality didn't do for another week-and-a-half. And
3 we think that's probative.

4 And then to have that same witness who did all these
5 things very quickly -- and I even say at some point, you were
6 diligent, Mr. Karlsson, right, to try to help put him at ease.
7 For him then to say, oh, I don't know, I don't remember, I
8 don't remember, I don't remember, that's something the jury
9 can consider and weigh in terms of the credibility when they
10 look at a document and say, here's somebody who acted really
11 fast at the time. He was a crackerjack doing all this stuff,
12 and now all of a sudden he doesn't remember a single thing.

13 That would be permissible in any trial. That's not
14 outside his personal knowledge. I'm trying to establish his
15 personal knowledge. If he remembered something, he could
16 testify to it. He says he doesn't remember. Just because
17 that's his answer does not mean it's inadmissible.

18 SPECIAL MASTER VANASKIE: I will allow it.

19 I think that takes us through 141:11.

20 MR. STANOCH: I think that's right, Judge.

21 SPECIAL MASTER VANASKIE: And now we go to 146.

22 MS. LOCKARD: I mean, I just -- before we get there,
23 I mean, there are certain references in some of these that
24 are -- aside from him not having personal knowledge, I mean,
25 there are questions that are inflammatory and prejudicial in

1 here.

2 And this may go to Judge Bumb, but, I mean, for
3 example, at line -- at page 140:17.

4 SPECIAL MASTER VANASKIE: I'm there.

5 MS. LOCKARD: And he's asking him, can you recollect
6 whether you learned that NDMA can be used as a poison?

7 I mean, that's just prejudicial, inflammatory.
8 There's no reference -- there's no discussion of poison. I
9 mean, it just comes out of nowhere. It --

10 SPECIAL MASTER VANASKIE: That's a good point. What
11 about that?

12 MR. STANOCH: Judge, none of this is coming out of
13 nowhere. This is coming out of the link that he said he
14 looked at and adopted in his email business record, and he's
15 saying he didn't remember all these things.

16 MS. LOCKARD: But if you're getting into what's in
17 the Wikipedia -- and I don't know if Wikipedia says it's
18 poison -- but that would be hearsay.

19 MR. STANOCH: Again, I'm not trying to prove it's a
20 poison or not. He looked at something and then he did
21 something based on what he looked at, whether it was true or
22 not.

23 SPECIAL MASTER VANASKIE: I'm going to sustain the
24 objection to the question on page 140, line 20 through 22 and
25 the answer on page 141, lines 1 and 2. And I'm doing it on

1 the basis of Rule 403. The danger of unfair prejudice
2 substantially outweighs its probative value.

3 Are we up to page 146 now?

4 MS. LOCKARD: Yes. I just -- the only other thing I
5 just want to make sure --

6 SPECIAL MASTER VANASKIE: Go ahead.

7 MS. LOCKARD: -- that we're all in agreement that
8 this is also subject to Judge Bumb's ruling with respect to
9 these questions like, you know, you understand that it could
10 be toxic to certain human organs, things like that.

11 THE COURT: Yes, it's subject to that ruling.

12 MS. LOCKARD: Okay. Human carcinogen and that kind
13 of language.

14 SPECIAL MASTER VANASKIE: Yes.

15 MS. LOCKARD: I think that brings us to page --

16 SPECIAL MASTER VANASKIE: I have it at 146.

17 MS. LOCKARD: That's where I am. Okay.

18 So our objection starts at 146, line 17 through 147,
19 line 3.

20 I guess, again, this is a toxic and known carcinogen
21 issue.

22 SPECIAL MASTER VANASKIE: David?

23 MR. STANOCH: I'm sorry, we're looking at 146:23?

24 MS. LOCKARD: I think 146:10 -- page 146, line 10,
25 that designation I think falls into the same bucket of Judge

1 Bumb, so I think we can move on to 147.

2 MR. STANOCH: So there's nothing else other than
3 Judge Bumb on 146:10 through 147:3?

4 MS. LOCKARD: Correct.

5 MR. STANOCH: Okay. What about your counter?

6 SPECIAL MASTER VANASKIE: This is the counter at page
7 150?

8 MR. STANOCH: That's what I was referring to, Judge.

9 MS. LOCKARD: Yeah, I think that is going to be
10 contingent on whether or not -- well, if it comes in, then we
11 want the counter. So I think it's contingent on Judge Bumb's
12 ruling, because it's him basically explaining, well, I'm not a
13 toxicologist, this was an early stage, so forth. So...

14 MR. STANOCH: If you want to defer, Judge, that's
15 fine.

16 SPECIAL MASTER VANASKIE: No. I mean, I would allow
17 the counter as well.

18 But if the original designation doesn't come in, the
19 counter doesn't come in.

20 MS. LOCKARD: Okay.

21 SPECIAL MASTER VANASKIE: Hold on.

22 Now we have a counter -- contingent counter --

23 MR. STANOCH: Yes, sir.

24 SPECIAL MASTER VANASKIE: -- at 153:24.

25 MR. STANOCH: Correct, through 156:9 minus

1 intervening objections.

2 MS. LOCKARD: So I believe 153:24 is already
3 designated.

4 SPECIAL MASTER VANASKIE: Let me look down there.

5 MS. LOCKARD: I mean, on the one we didn't have an
6 objection to it.

7 MR. STANOCH: If that's true, then I apologize.

8 SPECIAL MASTER VANASKIE: Yes, that's already
9 designated.

10 MR. STANOCH: Okay. My apologies.

11 MS. LOCKARD: Yes. So I think that's not an issue.
12 Okay.

13 MR. STANOCH: So I guess 147:6 is where we go,
14 everyone?

15 SPECIAL MASTER VANASKIE: That's what I have.

16 MS. LOCKARD: It's late in the day.

17 I think it's the same issue with respect to our
18 objection on personal knowledge and then the general causation
19 issue. Because it's getting to the research and you
20 discovered that it was toxic and a known human carcinogen. So
21 I think this falls into the same bucket.

22 MR. STANOCH: I would agree it is subject to whatever
23 is going to happen on general causation. I don't think any
24 other objections are well taken.

25 But I don't want to bicker about it if the Judge

1 doesn't want to focus on it right now.

2 SPECIAL MASTER VANASKIE: Yes, let's wait on the
3 general causation issue, and we may have to address it later.

4 MS. LOCKARD: Yeah.

5 SPECIAL MASTER VANASKIE: I was just going to say for
6 now it's deferred.

7 MS. LOCKARD: We don't waive any of the objections.
8 I mean, the issues all pretty much relate to general
9 causation. I mean, we also said it was cumulative. But
10 assuming we get some guidance from the Court on general
11 causation, I think we'll be able to work that out.

12 So 147:19.

13 MR. STANOCH: I think we go to 152. I don't want to
14 rush anyone, but I think we get to 152:9.

15 MS. LOCKARD: Let me make sure.

16 Yep. 148.

17 148:22 we had an objection as it's argumentative.

18 "Do you make a habit of sending inaccurate emails?"
19 We would object to that as harassing and argumentative.

20 MR. STANOCH: Should I address, Your Honor?

21 SPECIAL MASTER VANASKIE: Go ahead.

22 MR. STANOCH: The prior questions were all about an
23 email Mr. Karlsson wrote.

24 And then I simply asked him: At the time you wrote
25 it, did you believe it was accurate?

1 He says he can't remember. He can't remember if what
2 he wrote was true or false.

3 So I follow up: Sir, do you make a habit of sending
4 inaccurate emails?

5 I don't think so.

6 I'm simply following up on his fact that he's saying
7 he can't remember whether he tells the truth or not.

8 SPECIAL MASTER VANASKIE: If that happened at trial,
9 I'd sustain the objection. I'll sustain it as argumentative.

10 MS. LOCKARD: And that would go to his answer at
11 149:5 as well, I believe.

12 MR. STANOCH: Uh-huh.

13 SPECIAL MASTER VANASKIE: 149 through line 6.

14 MR. STANOCH: I agree.

15 MS. LOCKARD: Okay. So 152. We had an objection
16 starting at 152:16.

17 So our position is the whole line of questioning is
18 wholly irrelevant. The first question is about a product that
19 was in the development phase. It wasn't cleared to market.
20 It wasn't intended for the US. And it's not at issue in this
21 litigation. So 152:16 to 20 we believe is irrelevant,
22 prejudicial and should come out.

23 We have an ongoing objection to the general cause
24 issues and the references to toxic and carcinogenic.

25 And then I have the question about met with ZHP in

1 China about it is misleading and confusing and prejudicial.
2 He did not have a meeting with -- in China with ZHP about this
3 issue. He had a five-minute conversation at a conference he
4 was incidentally attending where this was discussed. So
5 there's no testimony, no foundation that there was a meeting
6 about this issue, and that's what it leads to believe -- leads
7 the jury to believe. He was at the same conference as the
8 prior witness where they're there among the industry, and he
9 asked a few questions about it, but it wasn't a meeting.

10 I also have an objection based on 602, personal
11 knowledge, regarding when Teva reported to FDA, which covers
12 lines 155:15 to 21 and his next objection.

13 MR. STANOCH: Judge, confess, I can't follow what
14 Ms. Lockard is doing. She's rattling off different objections
15 to different questions and different answers. I'm having a
16 very hard time following what just happened.

17 SPECIAL MASTER VANASKIE: I know. Let's slow down.

18 We're only going to go to 5:00 today, probably 5 of
19 5:00. We won't go beyond that. If we don't finish today, we
20 don't finish today. That's the way it is.

21 I don't want you to rush. And I want to try to get
22 this as correctly as possible.

23 So let's back up. We're on page 152, lines 9 to 21.

24 MS. LOCKARD: Okay. So we can take this one at a
25 time. And I don't mean to rattle, but -- I mean, this is a

1 very long designation. It wasn't clipped into short pieces.
2 It goes for three pages.

3 SPECIAL MASTER VANASKIE: Right.

4 MS. LOCKARD: So that's why there's numerous
5 objections.

6 SPECIAL MASTER VANASKIE: Gotcha.

7 MS. LOCKARD: We'll take one at a time.

8 The first objection starts at page 152, line 16, and
9 that's a relevance objection.

10 And the basis for the objection is that he's talking
11 about unrelated products, products that were in the
12 development phase, that were not marketed, that were not
13 cleared to market, that were intended for the European market
14 and is not at issue in this case.

15 And Judge Bumb has ruled with our motion in limine
16 that products that are meant in other markets, not in the US,
17 not at issue in this case, that testimony or evidence should
18 be excluded.

19 SPECIAL MASTER VANASKIE: All right. David?

20 MR. STANOCH: Your Honor, this ruling about other
21 products has been so contorted.

22 If you look just from the prior -- the prior page,
23 and what this is talking about is he's saying he shared
24 information about NDMA or a potential impurity with his R&D
25 colleagues, right, because they're developing a triple combo

1 valsartan product potentially with the ZHP API that ZHP is
2 saying is contaminated.

3 And all I'm asking him here, right, is that it would
4 be important for his R&D colleagues, who is developing a
5 valsartan product, to know that the valsartan API from ZHP
6 that they're talking about using for that is contaminated.
7 Right? That is the product at issue.

8 The valsartan API is what we're talking about. He's
9 saying this valsartan API has an issue. I, Stefan Karlsson,
10 think it's important. I better tell everyone who is looking
11 at the valsartan API. Why? Because it has significant
12 quality and use impacts.

13 I'm not trying to prove something about, oh, and yes,
14 this triple combo product sold in the Czech Republic actually
15 tested for NDMA. That's nothing about this at all. This is
16 all about his understanding that the valsartan API had an
17 issue and he's talking internally and going -- trying to do
18 everything he can to alert his colleagues who might be
19 involved with it that this valsartan API from ZHP has an
20 issue.

21 And all this question is, if it's contaminated,
22 that's important.

23 And he says: I shared the information we had at the
24 time. People were working through the issue. Et cetera, et
25 cetera.

1 MS. LOCKARD: So he's in R&D in Europe talking about
2 a product that's not at issue in this litigation. And we're
3 going to have to spend time to explain what was this whole
4 other product, what was going on in Europe, and it doesn't
5 have anything to do with the investigation that quality is
6 conducting involving the product at issue in this case.

7 So, of course, this was a huge issue industry-wide,
8 industry-wide. This was a big deal, so of course other people
9 in the company were talking about it, whether it impacted them
10 or not; but that doesn't mean that it's relevant to the issues
11 in this case. It's not probative of anything.

12 I mean, he was looking into it for R&D purposes.
13 Quality was looking into it for quality purposes related to
14 the actual product at issue in the litigation.

15 So it's just confusing.

16 MR. STANOCH: The only thing I would say, Your Honor,
17 is that he is being quicker and more diligent, we will argue
18 and show with evidence, about this issue from his perspective
19 than his counterparts in quality. And that's probative to
20 Teva's quality oversight and handling of the news about the
21 NDMA contamination.

22 MS. LOCKARD: Well, we disagree. We don't think it's
23 probative of the quality.

24 MR. STANOCH: We know -- you disagree with every
25 designation I have, I understand.

1 MS. LOCKARD: That's not true. In fact, I withdrew
2 several, several objections. And there were many that I
3 didn't object to. So let's be fair about this. I don't think
4 anything --

5 SPECIAL MASTER VANASKIE: There's no objection to
6 153, line 12 to 154, line 8?

7 MS. LOCKARD: No objection to that, correct.

8 SPECIAL MASTER VANASKIE: I'm trying to parse this.
9 So I would allow the question at 152, line 16, along
10 with the answer that concludes at 153, line 10.

11 MR. STANOCH: Okay.

12 SPECIAL MASTER VANASKIE: I would allow the question
13 at 153, line 12 with the answer that concludes at line 23 of
14 that page.

15 And that goes to 154, line 8. There's no objection
16 to that.

17 MS. LOCKARD: Agree.

18 MR. STANOCH: Understand.

19 SPECIAL MASTER VANASKIE: Now, you do have an
20 objection to the question at 154, line 9.

21 MS. LOCKARD: Correct. I think it's inaccurate and
22 misstates the prior testimony.

23 MR. STANOCH: Your Honor, before I heard -- I think
24 this was when Ms. Lockard was trying to argue what the word
25 "meeting" means, and that's obviously -- you know, it's

1 qualitative and for a jury to decide whether he had a meeting
2 or not. And that's not even what this says. Right?

3 At 154:9, you met with ZHP in person, albeit
4 briefly -- I qualify it -- as you said, in China about it.
5 Right?

6 Answer: Yeah.

7 I don't see what is misleading about that exchange.

8 MS. LOCKARD: You know, just to show that I can be
9 agreeable, I'll withdraw that objection to that part.

10 SPECIAL MASTER VANASKIE: All right.

11 MS. LOCKARD: I don't think it's critical.

12 So the remainder objection, the remaining objection
13 is to the section at page 155, lines 15 through 156:1.

14 And the objection there is lack of personal
15 knowledge. He's not -- as I said, he's in procurement. He's
16 not in the regulatory department that knows anything about
17 reporting to FDA. He doesn't even sit in the United States.
18 He's not involved in regulatory. He's not on the quality
19 team. He's in R&D procurement. This is far beyond his
20 personal knowledge as to when Teva reported to the FDA or why
21 they reported what they did or why they didn't report earlier.

22 SPECIAL MASTER VANASKIE: David?

23 MR. STANOCH: I will simply say, Your Honor, that
24 we've seen up until this point that he was personally
25 responsible in multiple direct communications with ZHP and

1 Teva about the issues cross-functionally, not just from an R&D
2 perspective, not just from a procurement perspective. There's
3 other emails that are not objected to and other testimony with
4 all manner of folks throughout the company. He's talking
5 about this. So someone who just talked about a timeline of
6 what's happening June 20, 21, 22, right. And then I simply --
7 and we saw the emails. And I simply ask him, do you know
8 something. And he goes, I can't comment on it.

9 That is his personal knowledge, he can't comment.
10 And then I follow up, because you weren't responsible for
11 telling the FDA. And he says, no, that's right.

12 So, again, this goes to he was able to do a number of
13 things quickly and arguably diligently that others at Teva
14 were not doing, and we should be permitted to juxtapose that
15 against what this person is doing at Teva when the other
16 quality people who should be doing it are not.

17 SPECIAL MASTER VANASKIE: I will allow it.

18 MS. LOCKARD: Okay. The only remaining objection to
19 that section or that long designation relates to the general
20 cause issue and references to toxicity, so I think we're done
21 with that designation.

22 SPECIAL MASTER VANASKIE: Okay.

23 MS. LOCKARD: I mean, the next -- so the next -- the
24 very next designation is the next question, which Mr. Stanoch
25 just raised.

1 I mean, I will just say that I heard Mr. Stanoch, and
2 it's a wild misrepresentation about what this witness's role
3 was. You know, he did get involved from an R&D perspective
4 and started asking questions, but it was not his
5 responsibility to deal with the FDA or to be involved in the
6 quality investigation on this issue. So we would stand by our
7 objection on this one as well.

8 SPECIAL MASTER VANASKIE: All right. Very well.

9 MR. STANOCH: And I think it's the same issue. And
10 I'll just state for the record, I vehemently disagree that I'm
11 wildly misrepresenting anything.

12 In fact, the testimony makes clear later that the
13 global head of -- executive vice president of R&D specifically
14 taxed Mr. Karlsson to follow up on issues about NDMA.

15 So I'll leave it at that.

16 MS. LOCKARD: So 157, line 6, again, do you know why
17 if the ZHP API impurity was known as early as June 20th, why
18 FDA's field alert -- Teva's field alert wasn't submitted until
19 July 3rd?

20 Again, I mean, this is -- plaintiffs deposed the
21 people, and they had a 30(b)(6) witness on regulatory
22 communications with the FDA. That's the witness who should be
23 addressing this. Asking an R&D European procurement person
24 about why US regulatory functions were not reporting or when
25 they were reporting should not be the subject of this

1 witness's testimony.

2 SPECIAL MASTER VANASKIE: That's what the witness
3 testified to, right?

4 MS. LOCKARD: Yeah. He lacks personal knowledge. He
5 says he has nothing to do with this, he doesn't know anything
6 about this. So it's 602.

7 SPECIAL MASTER VANASKIE: David?

8 Did we lose David?

9 MR. STANOCH: How about now?

10 SPECIAL MASTER VANASKIE: Yes, now we can hear you.

11 MR. STANOCH: My apologies to the madam court
12 reporter and the Court.

13 I was simply saying this is just like the last
14 designation which Your Honor allowed. I'm asking this
15 witness, a percipient knowledge, doing all these things in
16 realtime, about informing various people in the company about
17 the issues, asking him what his personal knowledge is. And he
18 answers it. And we should be allowed to present the evidence
19 of what this person, who is doing a lot of things on the
20 ground in realtime about it was doing, and what other people
21 at Teva were -- who should have been doing something were not
22 at the same time.

23 SPECIAL MASTER VANASKIE: I agree. I'll allow it.

24 MS. LOCKARD: Okay. I mean, just for the record, he
25 answers that he can't comment on it, that it would be handled

1 by the quality team, so...

2 SPECIAL MASTER VANASKIE: Exactly, exactly. That's
3 why I'm allowing it.

4 MS. LOCKARD: I understand. So he's made his point,
5 I guess.

6 SPECIAL MASTER VANASKIE: I know you don't want the
7 question to be out there. I understand that. But I think
8 he's entitled to ask the question, and the witness gave an
9 answer.

10 MS. LOCKARD: Okay. Understood. We can live with
11 that. It's not detrimental.

12 Okay. So 157:13. Again, I mean, it's the same
13 issues, but now it's really getting to be argumentative and
14 cumulative. So how many times is he going to ask about
15 reporting to FDA? I mean, he's really beating the horse on
16 this one. So it's -- in addition to the standing objections,
17 it's also cumulative and argumentative.

18 MR. STANOCH: Again, Your Honor, this is direct --
19 direct follow-up on the question we just had. And we're
20 asking him for his personal knowledge, and he answers and
21 that's it. I don't see how this is -- I'm not badgering him.
22 I'm asking slightly different questions based on what he's
23 answering. I don't see how it's different.

24 SPECIAL MASTER VANASKIE: I will allow it. It's
25 slightly different. And it's consistent with the approach of

1 ask a question a million times, but I will allow it.

2 MS. LOCKARD: So the next line is at page 158:7. And
3 again, this is badgering, argumentative, harassing. I mean,
4 he's established -- I think he's gotten on, you know, in the
5 evidence that Mr. Karlsson doesn't know, and now he's just
6 beating him up over it, which is unnecessary, and 403.

7 SPECIAL MASTER VANASKIE: This is at 158:7 through --
8 10 through 12?

9 MS. LOCKARD: Correct.

10 SPECIAL MASTER VANASKIE: Yes, I'll sustain the
11 objection. So that comes out.

12 MR. STANOCH: I'm just putting down that that excerpt
13 except 158:10 through 12 is allowed. So the question at
14 158:10 and 11 and the answer at 158:12 is out.

15 SPECIAL MASTER VANASKIE: Right. Correct.

16 MR. STANOCH: Thank you.

17 I'm sorry to be so plodding with it, Judge, but I
18 just want to make sure our notes are right.

19 SPECIAL MASTER VANASKIE: We want to make sure we get
20 it right.

21 MR. STANOCH: Yes, sir.

22 SPECIAL MASTER VANASKIE: 158:20 to 22 is what I have
23 next.

24 MS. LOCKARD: And I had in my notes that I had
25 actually withdrawn that one. I didn't see that noted on your

1 spreadsheet, but we withdraw whatever objection is there.

2 MR. STANOCH: If that was our typo in putting it
3 together for the Judge, we apologize.

4 MS. LOCKARD: Could have been mine, I don't know, but
5 it's a non-issue, so...

6 Okay. So 160 -- so this is a 407 and 403 objection,
7 and we also believe it should be excluded per the rationale of
8 Judge Bumb's ruling at the hearing on July 23rd. This relates
9 to subsequent remedial measures, things that -- when
10 Mr. Karlsson just sort of for the record -- I mean, you
11 probably have picked this up.

12 So Mr. Karlsson is, you know, sort of taking this on
13 from his perspective, and he's -- you know, plaintiffs'
14 argument is going to be he's digging in but quality isn't.

15 But he is digging in, and to the point where he
16 starts suggesting things that Teva might do or should be doing
17 or should be changing as they move forward.

18 And we had a motion in limine on the issue of
19 subsequent remedial measures, and particularly some of
20 Mr. Karlsson's emails where he goes through a list of things
21 that he thinks should be changed, and the judge ruled that the
22 items, the measures that he recommended, were subsequent
23 remedial measures and should be excluded.

24 And that was at -- I'll just for the record state,
25 that was at page 45 --

1 SPECIAL MASTER VANASKIE: Of the July 23rd
2 transcript, yep.

3 MS. LOCKARD: Correct. Right.

4 So we believe that the sections of this testimony
5 that are reading back what Mr. Karlsson's recommendations were
6 should be excluded based on the judge's ruling.

7 And that would include these questions like "might
8 also need to add a method to test the new impurity."

9 SPECIAL MASTER VANASKIE: Yes, I agree. This should
10 be sustained.

11 MS. LOCKARD: So the next was similar at page 162,
12 line 1.

13 SPECIAL MASTER VANASKIE: And for the same reason,
14 that would be sustained.

15 MS. LOCKARD: And then 163 --

16 MR. STANOCH: I'm sorry, can I catch up for a second
17 here, Judge?

18 SPECIAL MASTER VANASKIE: Yes. Sure.

19 MR. STANOCH: Give me one second.

20 MS. LOCKARD: Sorry, Dave.

21 MR. STANOCH: No. You're on a roll, Victoria, I
22 understand.

23 I'm not going to go backwards at this point, but,
24 Judge, the email that he's testifying to around 162, right, is
25 from ZHP regarding identification and explanation of the root

1 cause of the NDMA contamination. So this is different than
2 the one email which is at the end of the transcript, which
3 we'll get to, which Teva did move on and there's a ruling from
4 Judge Bumb on.

5 This is a little different in that it's ZHP
6 responding to questions for a capital action plan to Teva
7 about what's actually going on. And this is all from June of
8 2018. Right? So this is all happening at the same time about
9 the NDMA discoveries in June. This is not, you know, three
10 years after the fact Mr. Karlsson saying, yeah, we should
11 start testing for X, we should start testing for Y. This is
12 part and parcel of identifying what is wrong with the product
13 at issue.

14 It's not -- I think it's different in scope than the
15 email at the end of this transcript.

16 MS. LOCKARD: We would disagree. I don't think
17 there's any time requirement for subsequent remedial measures.
18 If there is a remedial measure that is recommended or adopted
19 in response to an incident, that's what the rule is for. And
20 that's exactly what he's talking about here.

21 MR. STANOCH: They're also not doing something, Your
22 Honor. They're not testing something. They're not doing
23 something.

24 And this might be an area where it may help us to
25 have the document. I'm not trying to bombard Your Honor with

1 another document in addition to the two we talked about this
2 morning with Mr. Nassall. But this is very targeted
3 questioning about a specific document from a specific time
4 period. And it may be worthwhile for us to get that in front
5 of you.

6 SPECIAL MASTER VANASKIE: Well, I'll make a ruling
7 now, and then you can get the document to me and we can see
8 whether that changes my ruling.

9 But right now I'll sustain the objection. And this
10 goes through 160:4 through line 13. And actually 160:4
11 through -- go all the way through 160:4?

12 MS. LOCKARD: It goes through 160:4 --

13 SPECIAL MASTER VANASKIE: I have 165, line 13.

14 MS. LOCKARD: 165:13.

15 MR. STANOCH: I think that's right.

16 MS. LOCKARD: I think that's right.

17 (Court reporter clarification.)

18 SPECIAL MASTER VANASKIE: It's 160, line 4 through
19 165, line 13.

20 Anybody disagree with that?

21 MR. STANOCH: I believe you're correct.

22 MS. LOCKARD: I don't disagree.

23 SPECIAL MASTER VANASKIE: All right. Now we're going
24 to page 255?

25 MS. LOCKARD: That's what I show.

1 Okay. So the objection as to this is based on
2 relevance, 402 and 403. And we also believe it's subject to a
3 motion in limine related to motion in limine 11 related to the
4 other products.

5 This is the discussion between Mr. Karlsson and
6 someone else in R&D, and she's asking in the first part of
7 this designation, has someone looked into the formation of the
8 carcinogen in other sartans' ROS or route of synthesis.

9 So she's basically saying, okay, we've got this issue
10 with valsartan, has anybody looked at the other products.

11 And we think other products is off limits, it's
12 prejudicial, it's not relevant. And that was similar to what
13 we were discussing before.

14 The issue here, though, is this is going to open up a
15 huge door to other products, because, keep in mind, the
16 nitrosamine issue impacted not just valsartan, not just other
17 sartans but the whole industry and other products that were
18 recalled subsequent to this. I mean, defense's position is
19 the valsartan issue sort of turned on the light to this
20 impurity issue and nitrosamines.

21 So the line Judge Bumb has drawn is that we need to
22 stay focused on the valsartan at issue in this case. And
23 there are other sartans, losartan, irbesartan, we also have a
24 stipulated agreement on a motion in limine in this case with
25 plaintiffs that we will not get into irbesartan and losartan.

1 So the other products she's talking about here, we
2 have stipulated agreement on that motion in limine. And the
3 only exception to it was the ZHP email related to irbesartan,
4 which has been the subject of lots of motions and sanctions
5 motions and so forth. But that was the only carveout.

6 And so they stipulated they wouldn't get into the
7 other sartans, and here we are with the testimony asking about
8 what's being done with other sartans.

9 SPECIAL MASTER VANASKIE: All right. David?

10 MR. STANOCH: No one is trying to prove anything
11 about olmesartan, candesartan, losartan, irbesartan, Judge.

12 This testimony is relevant as to two things. One is
13 it goes back to my point earlier where Ms. Lockard is arguing,
14 oh, this is just an R&D guy from Iceland, he's not involved,
15 he doesn't know what he's talking about. I'm paraphrasing. I
16 don't mean that pejoratively. But he's talking out of school.
17 He doesn't know what he's doing.

18 This is probative to the credibility of his earlier
19 testimony where he was a crackerjack doing all this research
20 and figuring things out himself very quickly, and this is now
21 the global head, right, of R&D for the entire Teva worldwide
22 is telling him, this man, Karlsson, who defendants are arguing
23 doesn't know what he's talking about, to follow up on all
24 these sartan issues and examine the routes of synthesis for
25 the formation of NDMA. Right?

1 So, number one, it's supportive and probative of the
2 credibility of his earlier testimony which we designated.
3 That's number one.

4 Number two, at this same time, this is July of 2018,
5 right, and they -- Teva tried to keep this out with Bumb, and
6 she let it in for -- she let it in over their motion in
7 limine, right, that Teva had released its hold of valsartan it
8 was selling in the US for products that did not have valsartan
9 API -- ZHP API. Right?

10 And this -- so at this very time, they're selling
11 other valsartan in the US into the market. And this is
12 showing that they released that hold and started doing it
13 again without having any real route of synthesis analysis.

14 And I know this doesn't prove that in itself, but it
15 goes with other evidence we have, which we're allowed to show,
16 that in terms of Teva's culpability and actions, not to prove
17 other valsartan was contaminated or losartan was contaminated,
18 but that its handling of this incident, that it put a hold on
19 everything but then it said, okay, all the other stuff is
20 fine, we're just going to recall the ZHP stuff, that that was
21 an inappropriate response to a quality issue, that they should
22 have taken the existing steps per their own SOPs, and this is
23 showing that.

24 SPECIAL MASTER VANASKIE: So you're saying it goes to
25 punitive damages?

1 MR. STANOCH: It does.

2 MS. LOCKARD: So let me -- so let me address that, a
3 couple of points there.

4 One is Judge Bumb saying that we can -- that
5 plaintiffs can offer the timeline that we released the hold
6 doesn't have anything to do with this. This is talking about
7 investigation into products that are not at issue. And just
8 like Judge Bumb would not let plaintiffs ask questions of our
9 quality witnesses about their investigation into irbesartan
10 and losartan, she would not let that. Her rulings preclude
11 that. The stipulation that we entered with plaintiffs
12 precludes getting into that. The fact that they released hold
13 on other products, that's a totally separate issue.

14 So the fact that quality people can't be asked about
15 what investigation they were doing related to other products,
16 then the procurement guy in Iceland certainly should not be
17 allowed to get into that. That's the first thing.

18 The second thing is, is this can't possibly go to
19 punitive damages, because the law on punitive damages is that
20 it needs to -- whatever the egregious culpable conduct is, it
21 has to relate to the injury to the plaintiffs.

22 Whether the R&D person in Europe is looking into
23 other sartans or not after the fact, after the recall has even
24 happened or after the disclosure has happened, that doesn't
25 have anything to do with the egregiousness of the conduct by

1 Teva prior to this that would have led to any injury to
2 plaintiff.

3 So we dispute the idea that this has anything to do
4 with punitive damages. We believe that it is in violation of
5 Judge Bumb's orders. We believe it violates the stipulation
6 among the parties. And it is, again, going to be confusing,
7 and it's going to mislead the jury.

8 Again, we're not saying he doesn't know what he's
9 talking about. He's a very good R&D person in Europe. But
10 we're not -- he's not some crackerjack investigator because he
11 looked something up on Wikipedia and started asking some
12 questions. That's not our position at all.

13 But what he's doing related to other products in
14 Europe that doesn't have anything to do with this case -- and
15 this is really expanding the points that this witness should
16 be talking about that are within his personal knowledge and
17 that he's qualified to talk about and that have anything to do
18 with this case.

19 SPECIAL MASTER VANASKIE: Well, I agree with you,
20 Victoria. And I think the objection should be sustained.

21 The problem I'm having is where do I draw the line,
22 or -- I had a note in my notes that said consider objecting to
23 entire inquiry through page 260, line 14.

24 But it goes beyond that, I take it. I know it's hard
25 to follow.

1 MS. LOCKARD: Yes. I'm just looking -- that's
2 exactly -- yeah. My notes say same as above.

3 So I think I would agree that that -- our objections
4 are consistent throughout all of those designations through
5 260, line 14.

6 SPECIAL MASTER VANASKIE: So I will sustain the
7 objections up to that point. And I think then we'll pick up
8 at page 261, line 6.

9 MS. LOCKARD: So actually, part of this also -- the
10 second part of the designation at 261, line 6 -- hold on a
11 second.

12 So Mr. Karlsson's answer implicates the same concern,
13 where he says at line 12: I can see what she's written where
14 she's asking if someone has looked through the routes for
15 other sartans.

16 So that is a follow-up from the prior discussion that
17 you just sustained our objection on.

18 SPECIAL MASTER VANASKIE: Yes.

19 MS. LOCKARD: The issue with the -- the other issue
20 with this is basically the questioning is misleading, because
21 counsel is asking questions about an email and saying, well,
22 Ms. Frederickson -- Fridriksdottir is suggesting that it's
23 important that Teva does its own.

24 And he's -- Mr. Stanoch is I guess paraphrasing, or
25 I'm not sure, but that does not appear anywhere in that email.

1 And so Mr. Karlsson's only response is basically --
2 what he should have said is, well, that's not what the email
3 says, but what he says is, I can see what she's written here
4 is that she's asking if someone has looked into the routes of
5 other sartans.

6 So I think it implicates the prior ruling, but it
7 also just -- it's a mischaracterization of the evidence and,
8 therefore, misleading and prejudicial.

9 MR. STANOCH: May I, Judge?

10 SPECIAL MASTER VANASKIE: Go ahead.

11 MR. STANOCH: These next few designations are
12 different from the ones above, because it's showing that
13 there's people realtime in Teva that are saying that Teva can
14 and should do its own analysis of routes of synthesis. And
15 other evidence will show that Teva did not do an appropriate
16 route of synthesis analysis of the valsartan API.

17 So when they say things like we can't do an analysis
18 of the route of synthesis or we don't have the route of
19 synthesis, this is showing -- this is contradicting that and
20 saying, look, no, no, no, people, important people in the
21 company think you should do your own route of synthesis
22 analysis.

23 And I'm not going to dicker about misleading or this
24 or that, but when I read a document, it's objected that I
25 shouldn't be reading a document. And when I orient the

1 witness to it and then ask a question, then it's misleading.

2 I feel I am in a damned if I do, damned if I don't situation.

3 MS. LOCKARD: Well, if the argument is that you want
4 this to show that it's something that Teva should be doing,
5 then that's a subsequent remedial measure, because --

6 MR. STANOCH: That wasn't -- it's not what I said.

7 MS. LOCKARD: -- you're saying they weren't doing it
8 before.

9 MR. STANOCH: That's not what I said.

10 MS. LOCKARD: Judge, his argument does fall within
11 the subsequent remedial measure objection as well, because
12 he's saying, okay, well, Teva -- Ms. Fridriksdottir is saying,
13 well, Teva needs to be doing its own analysis of the route of
14 synthesis. I mean, that's a recommendation for changing their
15 process based on the incident that happened.

16 I mean, this is all talking about recommendations
17 post-recall, post-notice.

18 MR. STANOCH: That's not true.

19 SPECIAL MASTER VANASKIE: Well, see, that's where you
20 lose me, Victoria, because if it's to find out what happened,
21 I don't think that's a subsequent remedial measure. If it's
22 to change your process so it doesn't happen again, that's a
23 subsequent remedial measure.

24 MS. LOCKARD: Right. But the investigation -- she's
25 in European R&D. She's not doing the investigation into what

1 happened for the US. She's concerned about what they're doing
2 for their development, that -- the developing products in R&D.
3 And she's saying, well, we need to start doing this process.

4 I mean, she's not looking back to evaluate. She's
5 not having conversations with quality and Tony Binsol in
6 testing to say, well, what were you doing to evaluate the
7 route of -- I mean, she's not investigating what happened
8 here. She's saying, let's make sure this doesn't happen
9 again. We need to make sure on the development side that for
10 our products, that we're making sure there's a route of
11 synthesis analysis. They have nothing to do with the quality
12 investigation that was being done in the US.

13 MR. STANOCH: There's no remedial measure here, Your
14 Honor. The question builds up to the pivot about the
15 appropriateness about taking a supplier's word for it that
16 there's no genotoxic impurity in the product. There's no
17 subsequent remedial measure.

18 And I'll also state for the record that I think that
19 subsequent remedial measure, it's not such a simple temporal
20 analysis that if something is written or said, you know, after
21 an event, then it's -- ipso facto, it's a subsequent remedial
22 measure. I think the rule requires a lot more than that. And
23 Teva has not satisfied the conditions for 408.

24 MS. LOCKARD: Plaintiffs are using this to show that
25 this should have been done before. I mean, that's exactly

1 what 408 goes to.

2 SPECIAL MASTER VANASKIE: I'm not sure.

3 We're going to break today at this time.

4 There's lots of objections here that have to be
5 handled yet for this witness.

6 This is our last witness, isn't it?

7 MR. STANOCH: Yes. Of the ones -- of the ones we
8 have.

9 MS. LOCKARD: I know. Mr. Stanoch isn't happy with
10 me because I haven't gotten him Tony Binsol's yet. And I
11 apologize to the Court and everybody here for that. I'm
12 trying to get through that. I will get that to Mr. Stanoch
13 tonight. We'll have to get it to Your Honor. And if you have
14 time to go through that, we could cover that one tomorrow.
15 We'll have the rest of Stefan Karlsson.

16 There are also a couple of short designations that
17 are in dispute between the defendants, the pharmacy counsel
18 and plaintiffs. And in the background we've been trying to
19 get some agreement on that, and we haven't been able to. And
20 we need to submit those to Your Honor as well, which could
21 probably be submitted this evening. Again, those are very
22 short, and that could be addressed tomorrow.

23 SPECIAL MASTER VANASKIE: Yeah. Let's adjourn for
24 today. I think we're all a little bit tired. Or I am anyway.
25 And --

1 MR. STANOCH: I join in the tired objection, Judge.

2 SPECIAL MASTER VANASKIE: What I'd like to do
3 tomorrow when we resume -- and I think we're resuming --
4 Larry, are you still there? At 10:00 a.m. tomorrow? Or is it
5 10:30?

6 MS. LOCKARD: I think you said 10:30. I don't mean
7 to speak for --

8 SPECIAL MASTER VANASKIE: That's fine.

9 MS. LOCKARD: -- for Mr. MacStravic, but I thought
10 this morning you said not starting earlier than 10:30, but I
11 can't remember the reason, though.

12 SPECIAL MASTER VANASKIE: Yes, Ann Marie.

13 (A discussion off the record occurred.)

14 SPECIAL MASTER VANASKIE: How about we start at 10:30
15 tomorrow?

16 MR. RAE: I was going to say that to the extent that
17 there is a need to start earlier, if I'm not able to join at
18 the beginning of the hearing, that's not a problem.

19 SPECIAL MASTER VANASKIE: Okay. We're going to start
20 tomorrow at 10:30. All right?

21 It would be helpful if when we get together tomorrow
22 at 10:30, we can put beginning and endpoints to lines of
23 inquiry so, you know, we're dealing with -- I know you're
24 dealing with this on a question-by-question basis, but they do
25 have topics. And if we could address it on a topic-by-topic

1 basis as opposed to a question-by-question basis, it might
2 move faster.

3 I don't want to prejudice anybody, so if within a
4 particular topic there's a question that you would like to
5 have treated specially, you can identify that for me. But I'm
6 just looking for a way to streamline this a little bit.

7 We've made a lot of progress, and I'd like to
8 conclude the deposition designations to the extent we can
9 tomorrow. If we can't, well, it will have to continue.

10 But we'll start tomorrow at 10:30 and go from there.
11 All right?

12 Any questions?

13 MR. STANOCH: No, Your Honor. That makes sense.

14 MS. LOCKARD: Not from me. Thank you.

15 SPECIAL MASTER VANASKIE: We'll see you tomorrow.

16 Thank you. Thanks, Ann Marie.

17 (Proceedings concluded at 4:53 p.m.)

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19 **FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE**

20 - - - - -

21 I certify that the foregoing is a correct transcript
22 from the record of proceedings in the above-entitled matter.

23

24 /S/ Ann Marie Mitchell 3rd day of October, 2024
25 CCR-RDR-RMR-CRR
Court Reporter/Transcriber